Exhibit 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

****

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

MDL No. 2875

****

HON ROBERT B. KUGLER

THIS DOCUMENT APPLIES TO ALL CASES

****

- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

Remote Videotaped Deposition of DAVID L. CHESNEY, commencing at 9:40 a.m., on the 21st of March, 2022, before Maureen O'Connor Pollard, Registered Diplomate Reporter, Realtime Systems Administrator, Certified Shorthand Reporter.

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Direction to Witness Not to Answer
PAGE LINE
None.

Request for Production of Documents
PAGE LINE
None.

Stipulations
PAGE LINE
None.

Questions Marked Highly Confidential
PAGE LINE
None.

P R O C E E D I N G S

THE VIDEOGRAPHER: We are now recording and on the record. My name is David Stone. I'm a legal video specialist on behalf of Golkow Litigation Services.

Today's date is March 21st, and the time is 9:40 a.m.

This is the deposition of David Chesney in the matter of In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation, plaintiffs, versus -- in the United States District Court, District of New Jersey, Case Number, MDL Number 2875.

This deposition is being taken via remote recording on behalf of the plaintiffs.

The court reporter is Maureen Pollard.

Counsel will state their appearances, and the court reporter will administer the oath.

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MR. SLATER: Adam Slater, Chris Gaddis, Julia Slater for plaintiffs.
MR. FOX: Thomas Fox, Skadden, Arps, for the ZHP defendants.
///
DAVID L. CHESNEY,
having been duly remotely identified and sworn, was examined and testified as follows:
EXAMINATION
BY MR. SLATER:
Q. Good morning, Mr. Chesney.
A. Good morning.
MR. FOX: Adam, I just want to make clear, this is being taken pursuant to the remote deposition protocol in the case?
MR. SLATER: I think that we have a remote deposition protocol.
MR. FOX: Yes.
MR. SLATER: Why are you asking me that?
MR. FOX: I just wanted to make sure, that's all.
MR. SLATER: I just have never

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been asked that question before in one of depositions we were doing remotely. I thought it was a trick question. I think so.
BY MR. SLATER:
Q. Okay. Good morning, Mr. Chesney.
A. Good morning.
Q. We're going to take your deposition now. You understand that, right?
A. I do.
Q. Have you been deposed before?
A. Yes.
Q. How many times?
A. Let's see. Four or five times, I guess.
Q. You understand you're under oath and must tell the truth, right?
A. Yes.
Q. If I ask you a question that for some reason you don't feel you can answer truthfully and completely, for any reason, just tell me. It may be that I mispronounce a word, or ask you a question that

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technically doesn't make sense to you because I don't understand something either from a regulatory perspective or legal perspective, whatever it may be, for any reason you're not clear on my question or don't feel like you can answer it, just tell me and we'll try to figure out what I need to clarify, and I'll try to do that. Okay?
A. Okay.
Q. Counsel may object. I think it would be unlikely he won't object during the course of the deposition. That's routine. It's never to signal an answer or how to answer, it's just preserving rights -- or at least it should never be to signal an answer, and I doubt it would be today, and I would expect it wouldn't be.
In any event, let your counsel object, and then answer the question, unless he tells you not to. Okay?
A. Yes, sir.
MR. SLATER: Chris, let's put up the deposition notice as Exhibit 1.
///

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(Whereupon, Chesney Exhibit Number 1 was marked for identification.)
BY MR. SLATER:
Q. Mr. Chesney, this is the deposition notice we served for your deposition.
Have you seen this document before?
A. Yes.
Q. Did you read it and go through all the requests?
A. Yes.
Q. Did you provide any documents to the lawyers that retained you in this case to be provided to us pursuant to this deposition notice?
A. Before I received the notice I did, yes.
Q. Okay. Once you got the notice, was there anything else that you identified and provided to counsel?
A. I don't recall that I did, no.
Q. When you say you don't recall,

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you don't recall if that happened, or you don't -- I'm unclear on your answer.
A. We had a discussion. The list of requests was quite broad, and I had difficulty interpreting the scope of some of the requests, and we discussed that.
At the end of that discussion, I believe counsel was going to submit a response, and I never heard anything further after that.
Q. At the end of that discussion when counsel worked through what the deposition notice was asking for, was there any information or documents that you provided to counsel to be provided to us?
A. No.
MR. SLATER: Okay. Let's take that document down, and put up as Exhibit 2 the response to the deposition notice, please.
(Whereupon, Chesney Exhibit Number 2 was marked for identification.)
///

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BY MR. SLATER:
Q. On the screen as Exhibit 2 is what we were provided as the response to our deposition notice. Have you seen that document?
A. No.
Q. One of the things we requested from you was the invoices in this matter.
MR. SLATER: And I guess, Chris, let's go to the invoices as Exhibit 3, and then we'll come back to the dep notice after, if that's possible.
(Whereupon, Chesney Exhibit Number 3 was marked for identification.)
MR. SLATER: Perfect. Thank you.
BY MR. SLATER:
Q. On the screen as Exhibit 3 are the invoices we were provided, and it shows that you began to work in this matter in June of 2021, is that correct?
A. That's correct.

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Q. Who contacted you and asked you to get involved in this case?
A. Frederick Ball of Duane Morris.
Q. Did you know Mr. Ball before he contacted you in June of 2021?
A. No.
Q. You'd never met him before?
A. I had not.
Q. Do you know how it was that he came to contact you? Did he tell you why he contacted you?
A. I don't recall. He probably told me at the time, but I don't recall now where he got my name.
Q. The response to the deposition notice, which we don't have to pull up, says that the invoices that were provided were in connection with the preparation of your expert report and your related testimony in this litigation. Is that what these invoices represent?
A. Yes. The majority of the time was the preparation of the expert report and the work I did researching information in

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that preparation.
Q. Other than writing this report and preparing for this deposition, have you done any other work for ZHP or any of its subsidiaries in connection with the nitrosamine contamination of its valsartan?
A. No.
Q. Have you been asked to consult or provide any opinions with regard to any disputes that ZHP may be having with any of its customers?
A. No.
Q. Okay. I added up these invoices which are dated between June 2021 and January of 2022 at $51,000.
Does that sound correct?
A. I think it's a little on the low side. I had added them up, and I think I came up with around 56.
Q. Okay. These invoices are up through January of 2022, the last one being $13,000.
MR. SLATER: Maybe we can go to that one, Chris, the last page.

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Perfect.
Q. Looking at the last page of this group of invoices, this is from January of 2022, $13,000, correct?
A. Yes.
Q. What amount of time have you spent since January up until today in connection with this matter?
A. I have that information on my time sheet records, but I don't have it with me. It's approximately 25 hours, more or less.
Q. Does that include your preparation right up until the point when we started the deposition?
A. I don't believe it includes the hours I spent this weekend looking over my report, but it's pretty close. It might be between 25 and 30.
Q. So 25 hours approximately before the weekend, and then maybe another five or so hours over the weekend before today's deposition?
A. Approximately, yes.

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Q. Okay. Thank you.
MR. SLATER: All right. Chris, let's go back to the deposition notice, if we could, please. Not the notice, I'm sorry, I meant the response. My bad. Thank you.
Q. I'm not going to go through all these requests, and you haven't read the responses, so I'm not going to go through that with you today in great detail. But what I would like to ask you is --
MR. SLATER: Let's go to request number 8. That's the -- go to the responses and objections to the requests, number 8. Perfect. Thanks, Chris.
Q. Looking at number 8, which we asked for any documentation of any research that you had performed with regard to the FDA's regulation of API and finished drug products, FDA inspections, current good manufacturing processes, and the risks and benefits of any angiotensin II receptor blockers or nitrosamines, we were told that

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you had worked at the FDA for 23 years, and have had an FDA-related consulting practice for more than a quarter of a century, and in those roles you'd informally researched countless issues over the course of your career, and that you have already submitted a list of your publications, and not conducted academic research regarding the list of topics. That was the response we were given. You can see that there.
Do you see that?
A. Yes.
Q. I just want to know talking to you now, have you in connection with this work -- well, rephrase.
Have you ever done any research regarding nitrosamines?
A. No.
Q. And that's true right up until right now?
A. Other than just briefing myself on the general issue and rereading some of the press that was out when it was made public and that sort of thing. No, no

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technical research.
Q. I think I saw in a few places in your report where you said you'd defer to scientific or to others with scientific expertise.
Is this one of the areas where you would defer to others with scientific expertise, meaning the nitrosamines and the risks posed by nitrosamines?
A. Yes.
MR. FOX: Objection to form.
Just make sure you slow down, David, so you give me an opportunity to make an objection on the record.
BY MR. SLATER:
Q. I'll just ask it again just because counsel objected, it may be that I talked too much in my question, happens from time to time.
Am I correct that you'd defer to other experts regarding the risks posed by nitrosamines as relevant in this case?
A. Yes.
Q. When I asked you if you'd defer

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to others, I didn't see you specifically cite any of their expert reports, you're just saying in general you would defer to others who have that expertise, is that correct?
MR. FOX: Objection to the form.
A. Yes.
BY MR. SLATER:
Q. Am I correct that in your experience both with the FDA and as a consultant following the time you left the FDA, you've never been involved in a matter that involved potential nitrosamine impurities in either an API or a finished dose product?
A. That's correct.
Q. Is this the first time in your career you've been involved in a matter where nitrosamines were a relevant factor in the analysis you were providing, meaning one of the constituent variables in the case was nitrosamines?
MR. FOX: Objection to form.
A. Yes.

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BY MR. SLATER:
Q. Before you were retained in this case, had you ever heard of NDMA?
A. Yes.
Q. And how did you know what NDMA was?
A. There were press reports involving the occurrence of NDMA in a variety of products, some gastrointestinal products as well as the valsartan-irbesartan family, and I read those press reports in the literature.
Q. Other than seeing press reports regarding the recent discovery of NDMA in various drug products, had you ever had any occasion to know what NDMA was before that?
A. No.
MR. FOX: Objection to form. Slow down, David.
BY MR. SLATER:
Q. I didn't see any discussion of NDEA in your report. Is that something you did not address at all in your report?
A. I did not address it.

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Q. I also saw no discussion of the TEA process for manufacture of valsartan API at ZHP. Am I also correct that is not something that you addressed at all in your report?
A. You're correct.
MR. SLATER: Let's take those down and go to Mr. Chesney's report. We'll mark that as Exhibit 3, along with the attached Exhibits A and B.
(Whereupon, Chesney Exhibit Number 4 was marked for identification.)
BY MR. SLATER:
Q. Mr. Chesney, you have in front of you on the screen your report which we've marked as Exhibit 3. I understand you're not scrolling right through it, but does that look like the first page of your report?
A. Yes.
Q. And I can tell you --
MR. GEDDIS: Adam, for the record it's Exhibit 4.
MR. SLATER: Did I say 3? I

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meant 4. Sorry about that. Let me rephrase.
BY MR. SLATER:
Q. Mr. Chesney, on the screen as Exhibit 4 we have your report. Does that look like your report right there?
A. Yes.
Q. And I have it as 59 pages, and then there's a digital signature for you on, it looks like, January 12, 2022. Is that when you put your signature on it and stamped this as a final report?
A. I'm not looking at it, but that sounds right.
Q. Do you have your report there in hard copy?
A. I do. I was just trying to flip to that page.
Q. Go ahead, take a look, and we'll just make sure we're on the same page of that.
MR. SLATER: You don't have to scroll to that, I don't think, Chris, because he has it.

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A. Yes, it was digitally signed on January 12th, that's correct.
Q. And that was the day when you finalized and confirmed your opinions in this case?
A. Yes.
Q. Does this report contain each of the opinions you formed in this matter?
A. Yes.
Q. You went through a number of facts and discussed a number of facts in the course of your report. Were those the facts that you felt were most important to you in supporting or formulating your opinions?
A. Yes.
MR. FOX: Objection to form.
BY MR. SLATER:
Q. I'm just going to digress for a second. We can leave that on the screen. I just want to ask you a few background questions.
Can you tell me how many times you've been retained as an expert witness in civil litigation?

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A. Four or five times.
Q. What is the bulk of the work you have done as a consultant since you left the FDA? It sounds like it's not litigation-based, so I'm curious what it is that you generally do.
A. I provide advice to clients on compliance strategy. I help them respond to FDA findings when they have inspections. I help them prepare for and manage FDA inspections. I conduct audits from time to time, some of which are general audits for compliance purposes, others of which are intended as mock FDA inspections to help them prepare for the real event. Any of a variety of other ad hoc issues that arise with clients that involve FDA compliance matters.
Q. Have you ever done any work in the past for ZHP, Prinston, Solco, or Huahai US?
A. No.
Q. Have you done any work for any of the other manufacturers or parties to this litigation, to your knowledge?

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A. The only two I recall seeing the names of are Teva and Mylan, and the answer in both cases is no.
Q. How about Aurobindo?
A. No.
Q. Hetero?
A. No.
Q. How about Torrent?
A. No.
Q. When you were an FDA investigator -- rephrase.
When you worked at the FDA, did your responsibilities include evaluation of manufacturers to determine whether there were GMP violations in the manufacture of API?
A. Yes.
Q. Same question with regard to manufacture of finished dose products.
A. Yes.
Q. In your work at the FDA, how much of your work was focused on that area, evaluation of potential GMP violations in the manufacture of API or finished dose?
A. I can't quantitate that

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precisely for you.
Q. Can you give me some idea of how many matters you investigated where that was the question?
MR. FOX: Objection to form.
A. Almost impossible, sir. I began my FDA career in 1972. Between that and my consulting career, I've spent nearly 50 years. It's very difficult to say how many of these issues I've dealt with over an extensive period of time like that.
BY MR. SLATER:
Q. So -- and I'm not going to push it. If you're not able to estimate the number of times that you addressed that issue at the FDA, I'll let it go if you tell me that.
A. I could not give you an estimate I would be confident about.
Q. Looking at your report, let me just find a good jumping off point.
MR. SLATER: Let's go to page 11, if we could, please, Chris.
Q. I was curious, on page 11 --

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rephrase.
On page 11 there's a heading "FDA Awards and Recognition" --
A. Yes.
Q. -- that says, "In 1990, I received the FDA Award of Merit, the FDA's highest award for individual achievement, for my work coordinating a major investigation involving deliberate contamination of imported produce sent to the United States."
When you say "deliberate contamination," what was that referring to? What happened?
A. Injection of grapes from a country of Chile with cyanide residues.
Q. I suppose you would agree with me that the deliberate contamination of a product regulated by the FDA would be a significant violation?
MR. FOX: Objection to form.
A. Yes.
BY MR. SLATER:
Q. Would you agree that the deliberate contamination of a product

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regulated by the FDA would be a GMP violation?
MR. FOX: Objection to form.
A. It depends.
BY MR. SLATER:
Q. Well, in this case where somebody injected cyanide into grapes, was that a GMP violation?
A. No.
Q. What was it a violation of?
A. Title 18 US Code Section 1365 of the Federal Anti-Tampering Act.
Q. If the grapes had been injected by somebody unrelated to the seller who was ultimately the target of your investigation, but the seller knew that they had been injected and still went ahead and shipped the grapes, would that be a violation?
MR. FOX: Objection to the form.
A. Yes, of course.
BY MR. SLATER:
Q. What would that be a violation of?

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A. Well, that could be a violation of the Food, Drug and Cosmetic Act if they knowingly shipped a product that they knew to be contaminated.
Q. If ZHP knowingly sold valsartan and knew that it had NDMA in it, would that be a violation of the -- of any regulations or laws?
MR. FOX: Objection to form. No foundation.
A. That depends.
BY MR. SLATER:
Q. If before FDA dis -- rephrase.
If before ZHP disclosed to the FDA that there was NDMA in its valsartan, if ZHP had been selling the valsartan for a period of time knowing that anyway and it still sold the product, would that have been a violation?
MR. FOX: Objection to form. No foundation.
A. It depends.
BY MR. SLATER:
Q. Depends on what?

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A. Depends on the levels of NDMA, what was known about it, whether they posed a hazard to people who might ingest the product. A variety of factors.
Q. So you're not able to form an opinion based on my question?
A. Not based on your question.
Q. Okay. If we go to page 12 of your report, the last matter listed is October 2021 and continuing, a "Contractual dispute between two pharmaceutical companies over cost recovery from a recall alleged to have been necessitated by GMP deviations at the contractor."
Can you tell me the name of that matter?
MR. FOX: It's subject to a confidentiality order. But, David, you can tell him the name of the matter.
THE WITNESS: Okay.
[redacted]

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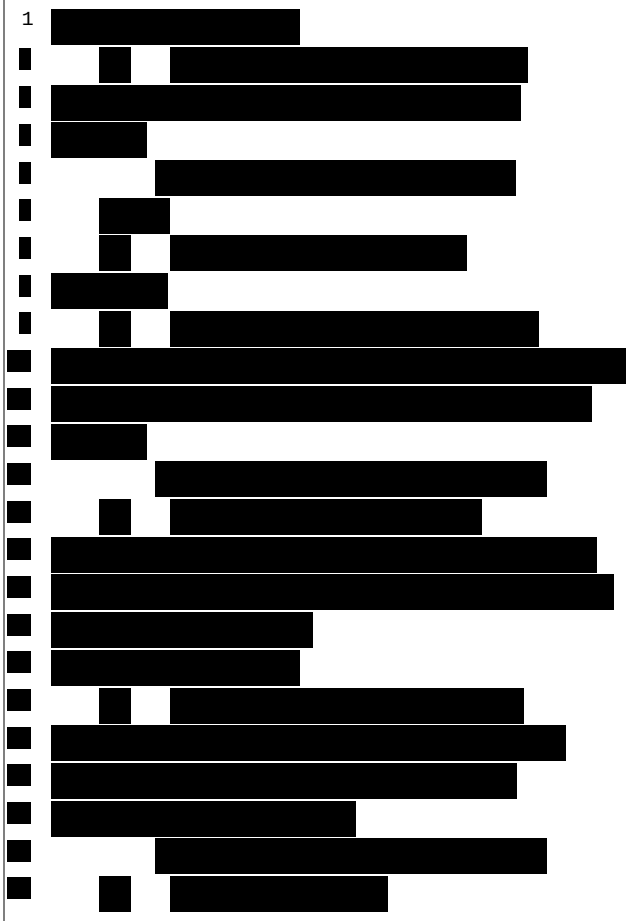

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Q. Good manufacturing practices requires a manufacturer to recognize potential creation of impurities so that they can be assessed, correct?

MR. FOX: Objection to form.

A. If information comes to light that raises that suspicion, GMP would require that it be looked into.

MR. SLATER: Chris, go to Exhibit A of Mr. Chesney's report, please.

Q. Mr. Chesney, Exhibit A to your report is your CV. Is that your up-to-date CV?

A. It is.

Q. Have you ever given any presentations as a consultant -- rephrase.

After you left the FDA, did you ever give any presentations regarding the application of GMP to the manufacture of API or finished dose?

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A. Not as the sole subject in the presentation.

Q. But that's something that's come up as part of some presentations?

A. Yes.

Q. Do you have those presentations still?

A. Some.

Q. Have you given any presentations -- rephrase.

Since the time you left the FDA, have you given any presentations regarding what a GMP-compliant risk assessment for a drug manufacturing process, whether API or finished dose, would involve?

MR. FOX: Objection to form.

A. Not as the sole subject of a presentation.

BY MR. SLATER:

Q. But again, something that's come up in the course of some presentations?

A. Yes.

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Q. Are those presentations you still have?

A. Some.

Q. When you were at the FDA, did you give any presentations regarding what GMP required in terms of a risk assessment in connection with the manufacturing process for API or finished drug?

A. No.

Q. When you were at the FDA, did you ever write any reports or sign off on any reports addressing whether or not there was a GMP violation in connection with the risk assessment for a manufacturing process for either API or finished drug?

MR. FOX: Objection to form.

A. Not specifically, no.

BY MR. SLATER:

Q. When you say "not specifically," does that mean -- what does that mean?

A. I reviewed and signed off on many reports involving API manufacturing. But in the era when I was working for the

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FDA, the requirements and expectations for documentation of risk assessment were not as detailed or well understood as they are today.

MR. SLATER: Let's go, Chris, if we could, to Exhibit B, please.

Q. And, Mr. Chesney, you're welcome to look at your hard copy report as well as I ask you questions if it's easier, whatever you think -- whatever is easiest for you. Okay?

A. Thank you. I have it open here. I'll try to work off the screen. If I need to stop, I'll let you know.

Q. Fair enough.

Exhibit B is titled "References," and it's my understanding those are the materials that -- well, actually let me rephrase it.

Exhibit B is titled "References," and there's a list of 129 items. Did you read all of those items?

A. I, at minimum, read them cursorily, but I didn't necessarily read

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every word in every item, no.

Q. With regard to the -- let me start over.

The first reference is the Expert Declaration of John Quick. Did you read that?

A. Yes.

Q. Number 2 is the Expert Declaration of Rena Conti. Did you read that?

A. I did.

Q. Did you find that to be relevant to the work you were doing?

MR. FOX: Object to form.

A. Mr. Quick's declaration, yes.

Dr. Conti's was helpful from a contextual standpoint, but I don't believe I relied on it to any great extent.

BY MR. SLATER:

Q. She is an economist. You didn't provide any opinions regarding economics or economic damages, right?

A. No, I did not.

Q. Number 3 is the Plaintiffs'

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Memorandum of Law in Support of their Motion for Class Certification of Consumer Economic Loss Claims. Did you read that?

A. Cursorily.

Q. And I didn't see any opinions in your report regarding whether or not this matter was suitable or not for class certification. Am I correct that's not an issue you addressed?

A. That is not an issue --

MR. FOX: Objection to form.

David, you have to slow up.

THE WITNESS: Sorry.

MR. FOX: Objection to the form.

You can answer.

A. That is not within my area of expertise, and I did not address it, no.

BY MR. SLATER:

Q. And I -- rephrase. The second -- rephrase.

The next reference is reference 4, Memorandum of Law in Support of the Medical Monitoring Plaintiffs' Motion for

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Class Certification. Did you read that?

A. Again, cursorily.

Q. What, if anything, about your cursory reading of those two memorandums of law was of any significance or use to you; anything?

MR. FOX: Objection to the form.

A. It was of use to me in understanding the context and the background, but not the details of fulfilling my remit in this matter.

BY MR. SLATER:

Q. Was there anything you read about in those briefs, those memorandum of laws -- memorandums of law that you said, Well, that's interesting, I should probably look at that, so -- and did you ask the lawyers, Hey, can you get me this document or that document, or this testimony or that testimony that you read about in the briefs? Did that happen at all?

A. I don't recall it happening. It was months ago.

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Q. With regard to the materials here, I can assure you we're not going to go through every single one of them because that would take a while, I want to ask you a few general questions about the references here.

Did you ask for any specific materials when you were engaged in this matter where you said, Look, this is what you have to provide me so I can formulate an opinion?

A. I may have asked for one or two items. I was provided with a great volume of material. The first thing I did was try to organize it, sort it out, see what was there.

And then as I got into the details of some of the items, there were things that I wanted to see that had not been provided.

Q. What, if anything, did you ask for that had not been provided to you in the course of your work in this matter?

A. One I recall was that when ZHP initiated the recall of their product, it is FDA's common practice to send what's called a

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recall classification letter. It's a template letter that says the agency agrees with the decision, and informs the recalling company of the class FDA has assigned to the recall.

I don't believe that was in the initial package, and I did ask for that document.

Q. Anything else that you requested?

A. I remember that one specifically. There may well have been others. This was a very voluminous document set, and as I went through it, if I found there was something I either could not find or felt I needed, then I would request it.

But I didn't keep a list of what I asked for separately from what was volunteered to me at the outset.

Q. You told me earlier that those facts that you found to be important to you in formulating your opinions were discussed in your report.

So can I trust that to the

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extent you read these materials and saw something that you felt to be of significance you related it in your report?

A. Yes.

Q. Item number 5 on the reference list is the Third Party Payors' Brief in Support of Motion to Certify Class. Did you read that?

A. I glanced at it.

Q. Is there anything of significance about that that you can point to now?

A. No.

MR. FOX: Object to the form.

BY MR. SLATER:

Q. Item number 11 is the Prinston Pharmaceuticals Audit Report, dated January 31, 2012, for inspection dates January 31, 2012. Did you read that?

A. Yes.

Q. I don't think I saw it referenced at all in your report in any specificity, is that correct?

A. I suppose. I don't recall

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referencing it. And there are several similar reports. I -- at this point by memory I can't distinguish one from the other.

Q. Do you know if you read each of the audit reports or not?

A. I looked at all of the listed reports, yes.

Q. And because they were not discussed in any -- at all in the report, can I assume that you didn't find anything to be of any real significance in those reported reports?

MR. FOX: Objection to form.

A. Not for the purpose I was asked to fulfill.

BY MR. SLATER:

Q. What did you have an understanding -- rephrase.

What was your understanding of your role? What were you asked to opine on?

A. I was asked to opine on what the documents in this matter caused me to think of the GMP compliance status of ZHP

facilities.
Q. Am I correct that your opinions regarding GMP were confined to ZHP and its manufacturing of the API?
A. Yes.
Q. I didn't see any discussion or opinions regarding Prinston, Solco, or Huahai US. Am I correct you gave no opinions regarding their actions or their compliance or noncompliance with GMP?
A. That's correct.
Q. I also saw no discussion of ZHP's manufacturing of the finished dose products. Am I correct that's not an issue you addressed in your report?
MR. FOX: Objection to form.
A. At least one of the FDA inspections touched on that, and I may have summarized some of the findings from that inspection. But I did not focus greatly on the finished dose for manufacturing issues.
BY MR. SLATER:
Q. I didn't see any opinions regarding ZHP's manufacture of finished dose

product. Is that correct, you didn't actually offer any opinions specific to that issue?
A. Not that I can recall.
MR. SLATER: Chris, can you go down to item number 19, please?
Q. Number 19 on this list is ZHP Genotoxicity Statement, dated July 6, 2016, and it has a Torrent Bates number.
Do you see that item?
A. I do.
Q. Is that something you read?
A. If it's on the list I did, yes.
Q. And I can tell you, and you can tell me if this comports with your recollection, that the genotoxicity statement is a representation that there were no genotoxic impurities in the valsartan API being sold by ZHP. Is that your understanding?
MR. FOX: Objection to form.
A. That is my recollection.
BY MR. SLATER:
Q. Did cGMP at that time in July

of 2016 require that such a statement be accurate?
MR. FOX: Objection to form.
A. All GMP statements are required to be accurate.
BY MR. SLATER:
Q. And this would be a GMP statement, correct?
MR. FOX: Objection to form.
A. It's a statement as to the presence or absence or impact if it is present of toxic compounds in the product. It's not really a GMP statement per se.
BY MR. SLATER:
Q. The genotoxicity statement whereby ZHP represented that no genotoxic impurities are present in the substance was certainly required to be a true statement if that's what they were saying, right?
MR. FOX: Objection to form.
A. Yes, any such statement submitted to the FDA would be required to be true, yes.
///

BY MR. SLATER:
Q. What would be the regulatory framework within which such a statement would be evaluated, if it turned out it wasn't true?
MR. FOX: Objection to form.
A. I'm not sure I understand your question.
BY MR. SLATER:
Q. You said that such a statement -- rephrase.
You agree with me that the statement that no genotoxic impurities are present in the substance was required to be true, right?
A. Yes.
Q. If that statement was false, what would be the regulatory or other framework within which that would be evaluated?
MR. FOX: Objection to form.
A. That would depend on the purpose for the submission of the statement.
///

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BY MR. SLATER:
Q. If the statement was made to allow a downstream purchaser of ZHP's API to be confident that the API did not contain genotoxic impurities, what would be the framework for evaluating that statement?
MR. FOX: Objection to form.
A. First of all, whether or not it was true and accurate. And it would not be a GMP statement per se. If it were submitted to the FDA directly because the agency requested it or in connection with a pending application or something of that sort, then it would come under the regulations for new drug applications or abbreviated new drug applications.
BY MR. SLATER:
Q. Any time that ZHP made a representation to the FDA as to whether or not there were genotoxic impurities in the valsartan API, that would come within the ANDA regulations, is that correct?
MR. FOX: Objection to form.
A. It depends on the context, but

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much of the time, yes.
BY MR. SLATER:
Q. Any statements ZHP made to the FDA about whether or not there were genotoxic impurities in the valsartan API was required to be a true and accurate statement, correct?
A. Yes.
MR. FOX: Objection to form.
BY MR. SLATER:
Q. You told me a few moments ago that your task in this matter was to review the documents provided to you and to evaluate the GMP compliance status of the ZHP manufacturing facility based upon your review of those documents, correct?
A. Yes.
MR. FOX: Objection to form.
BY MR. SLATER:
Q. Did you rely on the attorneys who provided those documents to you to make sure that you had all of the documents relevant to forming such an opinion?
A. Between the initial information they provided and responding to subsequent

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requests that I may have made, yes.
Q. You would agree with me that if there were material documents, meaning material -- rephrase.
You would agree with me that to the extent there were documents that would be material to your formation of that opinion that were not provided to you, that could potentially be problematic, correct?
MR. FOX: Objection to form. Calls for speculation.
A. I'm not aware that there were any such documents. And if I felt something was needed and I didn't have it, I requested it.
BY MR. SLATER:
Q. You told me about the one document you requested regarding the recall. Is there any other document you can recall that you asked for?
MR. FOX: Objection. Asked and answered.
A. I did a little independent research as well, looking at publicly

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available data on the FDA's website regarding the compliance history of ZHP. That was not supplied by the attorneys.
BY MR. SLATER:
Q. Ultimately your opinion is dependent on the materials you reviewed, correct?
MR. FOX: Objection to form.
A. Yes.
BY MR. SLATER:
Q. If I were to be able to show you documents during the course of this deposition where you would say, You know, that's a document that would have been material to me so I would have to look at that document and reevaluate my opinion, that would -- if that were to happen, that would place your opinion in question until you'd have the chance to review that document and determine whether it affected your opinion, right?
MR. FOX: Objection. Calls for speculation.
A. I have no way of knowing that

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without seeing the specifics.
BY MR. SLATER:
Q. Let me talk to you -- and let me be specific in what I'm asking you.
In terms of your approach to this case, your methodology, you've already told me that you relied on the documents that you reviewed to form your opinion. We've already gone over that.
What I'm getting at is, if I were to show you a document or ask you about a type of document and you said, Well, I didn't see that, and if that existed that would be important to me, something I would have needed to take into account in order to form my opinion in this case, if that were to happen, would you agree with me that you would then want to review that document and then offer an opinion based on everything you had seen inclusive of that document?
MR. FOX: Objection to form.
A. It would depend on the specifics.
///

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BY MR. SLATER:
Q. One of the things that you talked about in your report were internal standard operating procedures which you mention can go by various nomenclatures; standard operating procedures, standard management procedures, they can have various titles, but you talked about that concept in your report, right?
A. Yes.
Q. And I think -- you can correct me if I'm wrong, I think what you said was those internal -- and I'm going to call them generically standard operating procedures or SOPs, okay?
A. That's fine.
Q. I think you said in your report that to the extent a company actually adopts such SOPs as part of their GMP processes, they're required to comply with those SOPs.
Did I understand that correctly?
A. Yes.
Q. So if ZHP had internal SOPs

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relevant to the issues that you looked at, you would have expected to be provided those so you could take those into account in forming your opinion, correct?
MR. FOX: Objection to form.
A. Yes.
BY MR. SLATER:
Q. So for example, with regard to -- well, withdraw that.
If, in fact, there were internal SOPs from ZHP that you were not provided that relate, for example, to the change control process or the change control that was -- rephrase.
If there was a -- rephrase.
If there was an internal standard operating procedure from ZHP addressing the change in manufacturing process, you would have wanted to see that, right?
MR. FOX: Objection to form.
A. I did see one related to that.
BY MR. SLATER:
Q. Is it listed on your list of

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references?
A. No.
Q. Is it listed in your report in a footnote?
A. Yes.
Q. Is that 18.01?
A. That's a typographical error. I've discovered it should be 18.08.
The reason it may not be listed in the references is it was an attachment to the warning letter response that ZHP sent in, so it was included in another item that is referenced.
Q. Why are you saying that 18.08 should have been listed as opposed to 18.01?
A. Because I looked at it over the weekend and double-checked it against the footnote in my report, and found the report has a typo in that number.
Q. So the S -- it's actually an SMP.
A. Yes.
Q. Okay. So the SMP that you saw was 18.08?

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A. Yes.
Q. You did not see any of the other iterations of SMP 18, correct?
A. I did not, but the .08 version has a complete revision history, so I was able to tell from that what changes had been made over time.
Q. As you sit here now, do you know what the form of that SMP was when the manufacturing change process was being evaluated by ZHP?
MR. FOX: Objection to form.
A. I'm sorry, you said the form? I don't follow your question.
BY MR. SLATER:
Q. Let me ask you this. Did you ask to be shown the SMP that was actually in effect when ZHP was going through the change control process?
A. By retrospectively looking at the revision history, I believe it was version 5 or version 6, I don't recall as I sit here. But I was able to see what changes had been made since then in '08, and use that

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to determine what would have been there in that earlier iteration.
Q. Did you discuss that at all in your report?
A. No.
Q. Is this just an issue that you became aware of this weekend, as you said?
A. Oh, just the incorrect citation of the number I became aware of, yes.
Q. The wording of the SMP that governed the change control for the manufacturing process is an important document in this case, correct?
MR. FOX: Objection to form.
A. It's an important document, yes.
BY MR. SLATER:
Q. And the version that would be most significant would be the version that was in effect in 2011 when the manufacturing process change was being evaluated at ZHP, correct?
MR. FOX: Objection to form.
A. Yes, that would be important.

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Whether it would be most important or not is -- I'm not prepared to say, but it certainly would be important.
BY MR. SLATER:
Q. Well, in terms of whether or not ZHP complied with the SMP governing change control, the version that was in effect when ZHP conducted that change control review would be the one that you would want to look to to determine whether or not it was complied with, right?
MR. FOX: Objection to form.
A. I was able to use the revision history to see what changes had been made since that time, and as I sit here now, I can't explain that in detail because I don't have the document in front of me. But I concluded I had enough information there to establish that they did have a procedure for that.
BY MR. SLATER:
Q. Is the answer to my question yes, that the version that was in effect when the change was being evaluated, that would be

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the one that would be most significant because that would have been the one in effect at the time?
MR. FOX: Objection to form.
A. That would have been the one in effect at the time, and that would be the one that GMP would require them to follow, yes.
BY MR. SLATER:
Q. And you testified that you believed that version 5 or 6 would be the one that was in effect at the time of the change, and that's the one that would be most significant, that's your understanding?
MR. FOX: Objection to form.
A. I can't be positive without looking at the version history in the actual attachment that's referenced here, but from memory, I think it was in that vicinity. It was either 5 or 6. I'd have to look again to be sure.
BY MR. SLATER:
Q. If ZHP failed to comply with the SMP 18 version that was in effect when it did its change control review, then it

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violated GMP, correct?
MR. FOX: Objection. Form.
A. That would be a deviation from GMP, yes.
BY MR. SLATER:
Q. I'm not going to pull them out right now, but there were also some ICH documents that you referenced in your report as well, correct?
A. Yes.
Q. For example, ICH Q7A and Q7, that's the good manufacturing practice guidance for active pharmaceutical ingredients, that's an important document in this case, right?
MR. FOX: Objection to form.
A. The correct nomenclature is Q7. They dropped the A off of it a few years ago.
BY MR. SLATER:
Q. In the 2001 version it said Q7A, and then in 2016 they dropped the A.
Does that sound right?
A. Yes.
Q. So for our discussion today, we

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can just call it the Q7?
A. Yes.
Q. Was ZHP required to comply with Q7 at the time that it was evaluating the change in the manufacturing process as a matter of GMP?
MR. FOX: Objection to form.
A. In the US regulatory hierarchy, Q7 stands as nonbinding guidance, not as a regulation.
BY MR. SLATER:
Q. Well, if it's a nonbinding guidance, why does anybody look at it if it has no impact on anything that anyone is actually going to have to do?
A. Because there is no binding regulation for GMP for API, only a broad statutory requirement.
Q. In terms of how the broad statutory requirement to comply with GMP is interpreted, Q7 is actually a significant source, correct?
A. Yes.
MR. FOX: Objection to form.

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BY MR. SLATER:
Q. And in your industry, it's accepted that a violation -- rephrase.
And in your industry, it's accepted that a failure to comply with Q7 would amount to a GMP violation, correct?
MR. FOX: Objection to form.
A. Not exactly.
BY MR. SLATER:
Q. Are there circumstances where the failure to comply with Q7 constitutes a violation of GMP?
A. Are there circumstances -- pardon me. Say again? Are there circumstances when it does?
Q. Yes.
MR. FOX: Objection to form.
A. Yes.
BY MR. SLATER:
Q. I'm saying in and of itself where somebody would say, Well, because you didn't comply with this aspect of Q7, that constitutes a violation of GMP.
MR. FOX: Objection to form.

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Incomplete hypothetical.
A. That involves the application of judgment. It is not a linear correlation. If you deviate from a guideline, you're expected to have a justified reason why what you are doing to comply is as good as or better than what the guideline prescribes.
So there may be times you don't meet the guideline literally, but what you're doing is perfectly adequate.
BY MR. SLATER:
Q. I think what you're saying is if you're going to deviate from the Q7 guideline, you need to be able to explain why the alternative approach you took was acceptable?
A. That's correct.
Q. And acceptable would mean that it -- well, let me rephrase.
And acceptable would mean that your own process or your own approach accomplished the same thing that Q7 sought to approach, correct?
MR. FOX: Objection to form.

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A. Yes.
BY MR. SLATER:
Q. So, for example, if the issue was a -- the Q7 requirement that a thorough scientifically based risk assessment be performed in order to identify potential genotoxic impurities that may result from a change in manufacturing process, if ZHP failed to actually identify that potential impurity, ZHP would need to show why its approach either -- it would need to show why its approach which deviated from Q7 -- let me rephrase, because I think that I actually answered my own question.
MR. FOX: I'm going to object to it anyway, Adam.
MR. SLATER: I took it back. You can't object to the take-back.
BY MR. SLATER:
Q. If ZHP did not apply Q7 to its risk assessment for the manufacturing change to the zinc chloride process, ZHP would need to justify why it took an alternative approach, correct?

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MR. FOX: Objection to form.
A. Mr. Slater, your question assumes that that level of detail is in Q7, which it is not. If memory serves, Section 2.22 of Q7, line item 4 is one sentence that simply says that when deviations occur they must be investigated. It doesn't mention genotoxic impurities or anywhere near the level of specificity that was embodied in your question.
BY MR. SLATER:
Q. Can we agree when ZHP performed its risk assessment in connection with the manufacturing process change to the zinc chloride process that ZHP was required to apply current scientific knowledge?
MR. FOX: Objection to form.
A. Yes.
BY MR. SLATER:
Q. You said something earlier about from what you saw there was a process that ZHP had, and that's part of GMP, is that you have to have a process to follow, right?
A. Yes.

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Q. GMP also requires that the process be followed thoroughly and correctly, right?
MR. FOX: Objection to form.
A. Yes.
BY MR. SLATER:
Q. So going through the motions and saying, Well, we checked the boxes and we technically did a risk assessment, that's not enough; you have to actually actively perform the risk assessment and apply the available scientific knowledge in evaluating that process, right?
MR. FOX: Objection to form.
A. I don't -- I fail to understand the difference between saying you did a risk assessment and doing a risk assessment, which is what your question implied to me, sir.
BY MR. SLATER:
Q. Well, what I'm saying is, is it enough to just go through the motions and not apply the scientific knowledge that's available and just check the boxes and then you're okay?

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MR. FOX: Objection to form.
A. I fail to understand the thrust of your question. I really don't follow you.
BY MR. SLATER:
Q. Okay. I understand that you have told us you don't have the scientific expertise to determine whether or not -- well, rephrase. Let me ask you this, if I'm right.
Am I correct that you have told us in your report you do not have the scientific expertise to evaluate whether or not ZHP adequately took into account the scientific knowledge at the time of the manufacturing process change such that you can't offer an opinion as to whether or not ZHP met or did not meet current good manufacturing practices?
MR. FOX: Objection to form.
A. I am not a subject matter expert in process chemistry or pharmaceutical chemistry, nor was I when I was at the FDA.
The way things were done there and the way I do them in my consulting

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practice is in a multidisciplinary collaborative sense where I call on the knowledge and expertise of other subject matter experts to assist in areas where I don't feel I have all the knowledge and experience necessary.

That's the way these things are worked out both in the agency and in the consulting work that I do.

BY MR. SLATER:

Q. In response to my question, "am I correct," is the answer yes?

MR. FOX: Objection to form.

A. I don't -- I am not a subject matter expert in process chemistry or pharmaceutical chemistry, so there are limitations for how far I could take that analysis, yes.

BY MR. SLATER:

Q. And am I correct that because you do not offer any opinions regarding the scientific adequacy of the risk assessment, you're not offering an opinion at this time as to whether or not ZHP met its GMP

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obligations?

MR. FOX: Objection to the form. Misstates testimony.

BY MR. SLATER:

Q. Am I correct?

A. In my report I indicate those areas where I must defer to appropriate -- people with appropriate scientific expertise.

Q. And that's one of those areas, right?

MR. FOX: Objection to form.

A. It may be. As I recall it is, but I'm not looking at that part of the report at the moment.

BY MR. SLATER:

Q. Well, I'm asking you as you sit here right now, am I correct that because you're not able to offer an opinion as to whether or not ZHP's risk assessment was adequate from a scientific perspective, you're not in a position to offer an opinion as to whether ZHP's risk assessment was adequate from a GMP perspective --

MR. FOX: Objection to the

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form.

Sorry, Adam.

BY MR. SLATER:

Q. -- am I correct that you cannot do so because of your lack of scientific expertise?

MR. FOX: Objection to the form. Misstates testimony, no foundation.

A. I would require the assistance of scientific subject matter experts to have a fully formed opinion of that, that's correct.

BY MR. SLATER:

Q. Well, when you say to have a fully formed opinion, I just want to make sure before we get off this point that we're both clear.

You don't have an opinion as you sit here right now as to whether ZHP satisfied good manufacturing practices when it made the manufacturing process change because you're not able to evaluate the scientific adequacy of that risk assessment,

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is that correct?

MR. FOX: Objection to form.

A. I'm not able to determine independently whether it was feasible for them to have brought the scientific principles to bear beyond what they did, because I am not a pharmaceutical chemist or a process scientist, and not aware of what the state of the art may have been at that point in time. That's what I would need help on. I can't evaluate other aspects of the risk assessment.

And assuming the science is sound, I can then offer an opinion that if that is true, then the effort complies with GMP. But it's subject to validation by appropriate scientific expertise.

BY MR. SLATER:

Q. At this point you don't have an opinion as to whether ZHP met or did not meet GMP because you do not at this time have a basis to evaluate the scientific adequacy of the risk assessment. Is that a correct statement?

MR. FOX: Objection to form. Misstates testimony and his report.

A. Assuming the science is supportable I can form an opinion, but I would need additional input in order to be confident.

BY MR. SLATER:

Q. I understand what you could do if certain information were provided at a later date.

But as you sit here now, you're not able to form that opinion because you don't have that information one way or the other, correct?

A. That's correct.

MR. FOX: Objection to form.

BY MR. SLATER:

Q. I'm sorry, over the objection you said "that's correct," right?

A. Yes.

Q. You said that -- I think you used words to the effect of -- rephrase.

When you were talking a few moments ago you referred to the feasibility

of having certain scientific knowledge, or something to that effect. I know I'm not directly quoting you. But I think you said something to that effect.

Did I hear you right?

A. Yes.

MR. FOX: Objection to form.

BY MR. SLATER:

Q. If it was feasible for ZHP to be aware of the scientific processes that led to the creation of the NDMA impurity at the time it did its risk assessment, then it violated GMP by failing to identify that potential impurity, correct?

MR. FOX: Objection to the form. Misstates testimony, no foundation.

A. If it was feasible for them to apply appropriate science at that point in time and they failed to do so, it would raise certain questions and would require further study on my part and collaboration with the appropriate scientific experts so that I could fully understand the details before I

would be able to reach a conclusion I would be confident in. It would require study and discussion.

BY MR. SLATER:

Q. Well, I would like you to assume that it was feasible for ZHP to know at the time that it was performing its risk assessment on the zinc chloride process that under those manufacturing conditions DMF could degrade and create dimethylamine, and that it was also feasible to know that under those manufacturing conditions that dimethylamine could react with the nitrous acid that resulted from the sodium nitrate at the quenching stage, and that that reaction could form NDMA or other nitrosamines, I'd like you to assume that that was feasible for them to know at the time, and they did not -- as we know, they did not identify that potential impurity and that potential reaction, we know that.

So if my hypothetical is correct, ZHP violated GMP in its risk assessment, correct?

MR. SLATER: Objection to form. Incomplete hypothetical.

A. Part of a proper vetting of that position would require understanding whether analytical methodology existed that could detect NDMA at whatever level it might or might not be present, and how much reliability could be placed in that analytical methodology.

So that's another example of the sort of thing I would need the help of pharmaceutical chemistry expertise to better understand.

BY MR. SLATER:

Q. The analytical methodology would be GC-MS, gas chromatography-mass spectrometry, right?

MR. FOX: Objection to form.

A. That's one of, I believe, three methods that are out there now that were not at the time in question.

BY MR. SLATER:

Q. I'd like to expand my hypothetical to address the comment you just

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made, and I'd like you to assume that it was feasible based on technology available in 2011 for ZHP to have identified the NDMA if they were looking for it as a potential impurity. I'd like you to assume that technology was available.

Having expanded my hypothetical accordingly, you would agree that under those circumstances ZHP would have violated GMP in its risk assessment, correct?

MR. FOX: Objection to form.

A. Well, you're asking me to make a lot of assumptions, which I do not know whether they're true or not, and I frankly struggle with that. I'm not sure I can agree to that hypothetical.

BY MR. SLATER:

Q. We'll come back to it.

You said you normally work with a multidisciplinary team to form your GMP opinions in this type of a context?

A. I said that I did that when I was at the FDA, and that in consulting I still do that to this day.

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Q. That did not occur here, right?

A. It did not, because my retention was under a particular agreement, and I didn't have the benefit of being able to call upon colleagues and share details with them due to confidentiality.

Q. You did not rely on the opinions of any subject matter experts regarding the scientific questions here in forming your opinions. That has not occurred, right?

MR. FOX: Objection to the form. Misstates his report and references.

BY MR. SLATER:

Q. I'm correct, right?

A. I took what was available from the FDA communications and the record that I had in front of me and based my opinion on that.

Q. I didn't see any discussion in your report of you relying on any particular subject matter experts regarding the science to form your opinions. That's not something you did in your report, right?

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A. That's right.

MR. FOX: Objection to form. Misstates testimony.

A. What I did was I mentioned specifically in the report the areas where I was unable to carry my opinion beyond the point it's at because I would need to defer to others with appropriate scientific expertise. Those areas are highlighted.

BY MR. SLATER:

Q. I want to come back now to my hypothetical. And it's no secret I'm asking you these questions as a hypothetical because I think I can prove every single aspect of it very easily. So this is not some -- I'm just telling you this is no farfetched hypothetical. So let me -- having said that, let me rephrase.

Were you provided the report of Dr. Steven Hecht?

A. No.

Q. Do you know who he is?

A. No.

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Q. Were you -- rephrase.

Were you provided, other than Mr. Quick's declaration and Ms. Conti's declaration, any other plaintiff expert reports or declarations?

A. No.

Q. I'm going to try this one more time, but I'm going to try to do it more coherently.

Let me ask you this before I go on. Actually let me do this, actually, the way that I want to.

All right. I'm going to try to ask you the hypothetical in a little more condensed fashion now also addressing the analytical methodology issue that you questioned me on so I can put it all together in one question, and then we'll see if, maybe by me doing that, if you'll be able to answer that question, okay?

A. Sure.

Q. I'd like you to assume that at the time -- rephrase.

I would like you to assume that

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at the time ZHP was performing its risk assessment on the zinc chloride manufacturing process that it was scientifically feasible for ZHP to know that, under the manufacturing process conditions that were proposed, that the DMF that they had added to the process could degrade, and that one of the degradings from that could be dimethylamine, and that under the proposed manufacturing conditions that dimethylamine could react with the nitrous acid that would be present during the quenching phase due to the presence of sodium nitrate, and that that reaction could yield NDMA.

I'd like you also to assume that at the time it would have been scientifically feasible to apply testing to see if there was NDMA there if one were looking for it. I'd like you to assume those facts.

If those facts are true, you would agree with me that ZHP's failure to take into consideration what I just asked you about would have violated current good

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manufacturing practices at the time?

MR. FOX: Objection to the form. Incomplete hypothetical, calls for speculation.

A. If I understand your question correctly, Mr. Slater, if all those things were feasible and were known to ZHP, they should have taken them into consideration.

BY MR. SLATER:

Q. We know they did not, because you've seen their documentation, so we know ZHP never took into account the potential chemical reactions I went through with you, correct?

MR. FOX: Objection to form.

A. I can't reach that conclusion. ZHP submitted a tremendous amount of very detailed scientific analysis, a lot of structural chemistry diagrams and other things, and this is where my expertise drops off, and I would need others to look at that and determine whether they, in fact, understood the principles you've just outlined or not. I cannot reach that

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conclusion by reviewing the information they submitted.

BY MR. SLATER:

Q. If ZHP did not take into account the chemical reactions that I just described to you in my hypothetical, then they violated good manufacturing practices, correct?

MR. FOX: Objection to the form. Misstates testimony, calls for speculation.

A. What I -- I'm sorry? I heard an echo there, I guess. I thought someone was asking another question.

BY MR. SLATER:

Q. No, no one said anything. But let me just be clear on my question before you answer.

I'm going back to my original question, which is, assuming the accuracy of that hypothetical, assuming that it was scientifically feasible for ZHP to know those things, and assuming they did not take them into account, they violated good

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manufacturing practices in that risk assessment, correct?

MR. FOX: Objection to form. No foundation, misstates testimony, and calls for speculation.

A. The GMP requirement is very high level, it's for a thorough investigation. Nowhere does it specify what the elements of a thorough investigation are; it leaves that up to judgment.

And certainly if there is material information that was either not considered, omitted, whatever, then that risk assessment would be less than it should be based upon those facts.

BY MR. SLATER:

Q. When you say "less than it should be," that would mean not compliant with GMP, correct?

MR. FOX: Objection to form.

A. That calls for a conclusion that I'm not prepared to reach. It would be less than I would hope to see certainly.

But it's difficult sometimes to

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discern when you're talking about something would simply improve an otherwise compliant practice or make the difference between compliance and noncompliance.
BY MR. SLATER:
Q. Are you aware that there was -- well, let's jump forward a little bit, actually, since we're cruising along here. Just find a paperclip. We'll come back to this a little bit.
Let me ask you this: On your Exhibit B, did you actually review the change request form which laid out the evaluation that ZHP did of its change in manufacturing process to the zinc chloride process? Because I didn't see that referenced on your reliance list -- reference list, I should say.
A. I think it was incorporated in another document that is on that list, but it would take me some time to check back and find it. I do recall seeing that form, but I don't remember much about it as I sit here.
Q. I didn't see the change request

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form referenced anywhere in your report. Did I miss that, or am I correct that it's not referenced?
MR. FOX: Objection. Asked and answered.
A. It may not have been referenced by that name. I think it was a part of another document set that I reviewed and relied upon. And if memory serves, I believe it was the response to the warning letter, but I would have to go back and check through these references to determine that for certain.
BY MR. SLATER:
Q. The documentation of the risk assessment for the change in manufacturing process, that documentation would have been very important to you in forming your opinion here, correct?
MR. FOX: Objection to form.
A. Yes.
BY MR. SLATER:
Q. Yet there's no place in your report where you actually discuss that

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document at all, correct?
A. What do you mean by "that document"? Which document are you referring to?
[redacted]
anywhere in your report or discussed at all in your report. Am I correct?
A. I don't recall specifically citing it. I do recall seeing it.
Q. The change request form documenting what was done and what was considered would be a critical document to you in forming an opinion as to whether or not ZHP met its GMP obligations, right?
MR. FOX: Objection to form. Argumentative, and misstates prior testimony. Asked and answered.
A. Subject to input regarding the rigor of the science, yes.
MR. SLATER: Counsel, you keep saying that I'm misstating testimony.

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I don't understand why you keep saying that. I'm not stating his testimony.
I mean, I think we have to at some point -- I would ask you politely if we can just limit the objections to legitimate objections, please.
MR. FOX: It was a legitimate objection, Adam. You previously asked him whether it was important, now you're asking him whether it's critical. You were changing the question on him, and you had already asked about that.
BY MR. SLATER:
[redacted]

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[redacted]

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Q. As a matter of ICH guidance, if something is deemed a critical change, it requires a higher degree of scientific rigor in performing the risk assessment, right?

MR. FOX: Objection to form.

A. Generally speaking, yes.

BY MR. SLATER:

Q. Do you know whether or not -- well, rephrase.

You said you think that you saw the change request form as an attachment to another document. Did you ever ask counsel, Is this the complete change request form with all attachments?

A. I don't recall ever asking that question, no.

Q. Do you have any knowledge as to whether or not the change request form that you think you saw attached to another document was the complete change request form with all attachments? As you sit here now, do you have any idea?

A. I do not as I sit here now.

Q. And without seeing the complete

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document and comparing it to what you did have, you don't know whether there's material information that you didn't have available to you, right, by definition?

A. I'm not sure I understand your question, sir.

Q. Well, you don't know what you don't know, and since you don't know if you saw the complete document you don't know if you were missing material information from the change request form and its attachments, right?

MR. FOX: Objection to form.

A. If there was material information that was not made available to me, I'm not aware of that, and yes, it would be of concern.

BY MR. SLATER:

[redacted]

A. I don't recall.

Q. Would that be an important

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consideration in forming an opinion as to whether ZHP complied with GMP?

MR. FOX: Objection to form.

A. That's another example of something that I would ask for help from a pharmaceutical chemistry expert to evaluate, but yes, the outcome of that discussion would be important.

BY MR. SLATER:

Q. Were you curious when you were writing your report as to what impurities ZHP considered -- let me rephrase.

When you were writing your report, were you curious as to what potential impurities ZHP considered as part of its risk assessment for the zinc chloride process? Were you curious as to what they looked at?

A. I'm not sure I understand what you mean by was I curious. I reviewed the record, I saw what they did consider, I saw how they documented it, I stated, I think fairly clearly, where my limitations were in my ability to evaluate the science.

Was I curious as to whether

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they looked for certain other things that they might have had no reason to believe were there? No. GMP does not require that you look for things you have no basis to believe are present.

[redacted]

BY MR. SLATER:

Q. As you sit here now, did you say anything about that in your report?

A. Again, I'd have to go through the report to be certain.

[redacted]

Are you saying it might be in the report and you'd need to check your report to see if that's in there?

A. I don't recall that it's there,

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but I wouldn't be prepared to say that definitively without going through the report.

Q. And as you sit here now, are you able to tell me one way or another whether or not -- well, let me ask you this.

As you sit here now, do you have an assumption as to whether or not ZHP considered the potential formation of NDMA or any other nitrosamines as part of the zinc chloride manufacturing process when it performed its risk assessment? Do you have an assumption one way or the other as to whether that was considered?

A. My assumption would be that they did, absent information to the contrary. But I don't recall what those documents said without going back and looking at them again. This was an incredibly voluminous data set, and I don't carry it all around in my head.

Q. What's the basis for that assumption that they did consider the potential formation of NDMA or other nitrosamines as part of the risk assessment?

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A. It's the impression I got of the thoroughness and completeness of the documents that I reviewed from ZHP, the interactions between them and the FDA staff, the FDA questions that came back to them, the entire dialogue that took place there.

Ultimately they did, of course, find those residues in certain batches, and they did the responsible thing and conducted a recall, so at some point in time they did make that identification. I believe that was in 2018.

Q. When you say "they did the responsible thing," do you mean telling their customers and the FDA that there was NDMA in the valsartan?

A. Once they knew that, yes.

Q. When you say that's the responsible thing, it's not only the responsible thing, it was the legally required thing to do, right?

A. Yes.

MR. FOX: Objection to form.

///

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BY MR. SLATER:

Q. As soon as ZHP knew that there was NDMA in its valsartan, it was legally obligated to inform all of its customers and the FDA, correct?

MR. FOX: Objection to form. Calls for a legal conclusion.

A. The regulatory requirement is for them to report that to the FDA in the form of a report called a field alert report.

BY MR. SLATER:

Q. And it's your testimony based on the materials you saw that you understand that ZHP complied with that field alert report regulation in June of 2018?

A. They notified the FDA.

Q. It's your understanding that ZHP notified its customers and the FDA immediately upon learning that there was NDMA in its valsartan? Is that your understanding from what you reviewed?

MR. FOX: Objection to form.

A. The word "immediately" is one I have difficulty with. They did it very soon

thereafter. I don't know what you mean by "immediate," but it was in very close proximity time-wise to that, yes.

BY MR. SLATER:

Q. The field alert report regulation provides three business days to provide that information to the FDA, right?

A. Yes.

Q. Is it your understanding that ZHP reported that there was NDMA in its valsartan within three days -- business days of learning of that?

MR. FOX: Objection to form.

A. The difficulty with that is it's very difficult to determine in many cases when the clock starts.

I believe they did the responsible thing by reporting it. Once they had certainty as to that information they told the FDA about it, and they did conduct a recall on a voluntary basis.

BY MR. SLATER:

Q. Was the notification of the presence of NDMA in the valsartan to

customers and the FDA required by good manufacturing practices?

A. No.

MR. FOX: Objection to form.

BY MR. SLATER:

Q. Did good manufacturing practices require that -- well, rephrase. I'll get back to it.

Coming back to what ZHP did as part of its risk assessment -- well, rephrase.

I was asking you before about whether ZHP considered the potential formation of nitrosamine impurities including NDMA, and you said your assumption was that they did consider that, right?

MR. FOX: Can you repeat that, Adam? I missed that.

MR. SLATER: Sure.

BY MR. SLATER:

Q. You told me a moment ago that you assumed that ZHP did as part of its risk assessment take into account the potential formation of nitrosamines as part of the zinc

chloride process during its risk assessment. You told me that you assumed they took that into account, right?

A. It would appear that they did from the depth of the scientific information they submitted. But again, that's one of those areas where I would turn to the subject matter expertise -- or a person with appropriate subject matter expertise to help me understand how far they carried things and whether that was sufficient to achieve those ends. I didn't --

Q. Go ahead, I'm sorry.

A. I was going to say I made no attempt to evaluate the science independently.

Q. Whether or not ZHP considered the potential formation of nitrosamines as part of the zinc chloride process is an important fact you would want to know, right?

MR. FOX: Objection to form.

A. Along with whether or not it was even reasonable for them to consider that at that point in time. I think that's the

other aspect of this. There's nothing in GMP that requires you to look for things you would have no basis to believe were there. And that's why the state of the art of the science at that moment in time is important for me to understand in tandem with the other information.

BY MR. SLATER:

Q. Well, my first question is this. One important fact for you to consider in this matter would be whether or not ZHP considered the potential formation of nitrosamine impurities as part of the proposed zinc chloride process when it performed its risk assessment.

Would you agree with that statement?

A. It would be helpful to understand that, yes.

Q. Did you ask the lawyers who retained you if there's any information available to answer that question one way or another?

A. I don't recall asking that

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question.
Q. That's my question. I want to know if you asked them for that. Okay.
A. No.
[redacted]

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[redacted]
MR. FOX: Is this a good time for a break, Adam?
MR. SLATER: I need a couple more minutes. I'd like to continue. I don't want to just arbitrarily take a break now.
BY MR. SLATER:
Q. If there was deposition testimony from corporate representatives of ZHP that definitively answered that question,

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would you like to have been provided that deposition testimony?
A. Yes.
Q. If such testimony exists one way or another, you would actually expect that that would have been provided to you so that you could perform your function here, right?
A. It would have been helpful.
Q. Can you think of any legitimate reason why the lawyers who hired you would not have provided you that deposition testimony if, in fact, it exists?
MR. FOX: Objection. Argumentative.
A. I don't know what the basis was for the document set that I was provided. I can't speculate about what might have been in their minds as to what I would need or what I wouldn't.
BY MR. SLATER:
Q. If there was a feasible scientific basis for ZHP to know that nitrosamines could potentially be formed by

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the zinc chloride manufacturing process that was being proposed, if that was feasible to know, and if the technology existed for ZHP to feasibly test to see if a nitrosamine was being created by this new manufacturing process, then ZHP would have been required to carry out such testing to see if nitrosamines were being created as part of its risk assessment, correct?
MR. FOX: Objection to form.
A. That would have been the right thing for them to do. The requirements don't speak to that level of detail, but that would have been a reasonable thing for them to do, yes.
BY MR. SLATER:
[redacted]

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[redacted]

BY MR. SLATER:

Q. But you, as somebody who holds themself out as an expert on GMP, would look at what the company actually put in force in its own internal SOPs to address its own business, and based on what you've seen you would agree GMP as applied by ZHP would have required that to be done, right?

MR. FOX: Objection to form.

A. If their procedure called for identification or quantitation of known potential impurity risk and they failed to do so, then yes, that would be a failure to follow their own procedure, which by extension is a failure to follow GMP.

BY MR. SLATER:

Q. And you would certainly expect that ZHP or any similar manufacturer would have an internal SOP that would require it to

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identify new impurity risks if they were going to change a manufacturing process, right?

A. That's something they should be considering, yes.

Q. That would be required by GMP under those circumstances, right?

MR. FOX: Objection to form.

A. Broadly, yes, but not specifically.

BY MR. SLATER:

Q. Well, if you were brought in by ZHP or a similar company and asked, We're changing our manufacturing process for this API, would GMP require that that evaluation that we're going to perform evaluate whether any new impurities are being formed, you would say yes, right?

A. Yes.

Q. If you want to take a break -- I'm happy to keep going, Mr. Chesney, your counsel asked if we need a break, I don't need one. I'm happy to keep going because I'm hoping to get done in the afternoon, but

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it's completely up to you. If you want to keep going, I'll keep going.

MR. FOX: We've been --

THE WITNESS: Go ahead, Tom.

MR. FOX: What did you say, David?

THE WITNESS: I was just going to say I could use about ten minutes at this point.

MR. SLATER: All right. Let's take ten minutes.

THE VIDEOGRAPHER: The time is 11:25 a.m. We are off the record.

(Whereupon, a recess was taken.)

THE VIDEOGRAPHER: The time is 11:36 a.m. We are back on the record.

BY MR. SLATER:

Q. I want to talk a little bit about the significance of the risk assessment for a couple minutes with you.

The risk assessment performed -- rephrase.

The risk assessment that was

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required to be performed by ZHP has significance for process validation in the sense that you have to identify potential impurities so that you know to test for them.

Is that a true statement?

A. Generally speaking, yes.

Q. So identification of the potential impurities from a new manufacturing process is really a very important threshold step pursuant to GMP, correct?

MR. FOX: Objection to form.

A. To the extent that it's feasible to do so and you know what to expect, yes.

BY MR. SLATER:

Q. When you say you know what to expect, meaning you know that this is a potential impurity so you know that you need to test for it?

A. Yes. You don't need to conjure up things that there's no rational basis to believe what happened.

Q. And this risk assessment is not supposed to be based on guesswork, it's

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supposed to be based on scientific analysis, right?
A. Yes.
MR. FOX: Objection to form.
BY MR. SLATER:
Q. For example, in a situation like this, a company like ZHP would be expected by GMP to have process chemists evaluating the proposed chemical reactions, and to bring their scientific knowledge to bear to identify the potential impurities that could result, right?
A. Yes.
Q. And they would -- rephrase.
And these process chemists would be expected to not only bring to bear their own knowledge that's in their mind, but also to, to the extent they don't know the answer, to research available medical literature, right?
Let me rephrase because I went all over the place. I meant to say scientific.
And those process chemists

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would be expected to not only employ their own personal knowledge, but also to research scientific literature as well to the extent that it existed, right?
MR. FOX: Objection to form.
A. Any literature reports they're aware of, they should be taken into consideration if they're relevant.
BY MR. SLATER:
Q. And this should be an active process of research and evaluation, right? They should be actively looking to make sure that they turn over the stones that can be turned so they don't miss something, right?
MR. FOX: Objection to form.
A. Well, yes. Within reasonable limits. You don't have to stay in search mode forever. There comes a point in time when you've consulted appropriate reference materials and feel that you have enough to go on. That's a matter of judgment.
BY MR. SLATER:
Q. One of the other important reasons why potential impurities need to be

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identified during the risk assessment is so that not only the process validation can be thorough, but also so that ultimately the specifications for what needs to be tested and what the levels that should be tested for so that those can be set as well, right?
A. Yes.
Q. And I guess the specifications is sort of the other side of the coin from the process validation. Is that a fair assumption? The process validation is when -- it actually doesn't make sense. You don't have to answer that. You roll your eyes, I know I move on.
If there was a GMP violation in the risk assessment, as I have proposed to you through my hypothetical, and ultimately ZHP should have but failed to evaluate the potential nitrosamine impurities that could have resulted from the zinc chloride process, if that's so, and then they went ahead and used that manufacturing process, that process would not be cGMP compliant based on the GMP violation in the risk assessment, correct?

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MR. FOX: Objection to form.
A. That would require me to accept a lot of the assumptions that you're building into your hypothesis.
BY MR. SLATER:
Q. I'm asking you to accept those assumptions.
If those assumptions are -- if the answer is yes, if you accept them, am I correct that the manufacturing process itself would not be GMP compliant?
MR. FOX: Objection to form. Incomplete hypothetical.
A. Well, that's not the way I would put it, Mr. Slater, that the GMP -- or that the manufacturing process would not be GMP compliant. I would simply say there was material information about the risks inherent in that process that had not been identified.
The point in time when this took place, if I remember correctly, was 2011, 2012, something like that. Again, without referring to the references, I can't be sure. But I think the FDA in their public

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statements later on indicated the general awareness of these risks wasn't really known in the industry or even to the regulators until much later. So that's why I'm a little concerned about the validity of some of these assumptions.
BY MR. SLATER:
Q. And I'm going to go through that with you a little more. But let me ask you this. I want to go back to what I was asking.
If you make the assumptions that I've asked you to make as to the inadequacy of the risk assessment, and if you make those assumptions, which you can assume those things are hypothetical as an expert as you know, and the risk assessment violated GMP, would it also be a violation of GMP to then manufacture with that manufacturing process which is creating NDMA?
MR. FOX: Objection to form.
A. Well, if we can be clear that I'm not accepting the assumptions, just viewing them purely as hypotheticals, then my

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answer would be yes. But I'm really not clear that the underlying assumptions are accurate at this point.
BY MR. SLATER:
Q. At the time ZHP developed the zinc chloride process, to your knowledge was any other API manufacturer for valsartan, or any other sartan for that matter, using the zinc chloride process in the world?
A. I don't know.
Q. Are you aware of whether or not there was any potential risk of the creation of nitrosamines with the original manufacturing process for valsartan, for the branded form of the drug, did you ever look to see whether or not that manufacturing process had a similar risk?
A. I did not because that would get into process chemistry, which is outside my area of expertise.
Q. Give me one second.
Sorry, I'm just digging through a pile because my goal in life is to not make the deposition last longer than necessary.

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Okay.
A. That's appreciated, sir.
Q. There's no reason to go longer than necessary.
MR. SLATER: Okay. Let's go, Chris, if you can do this, I want to go to what I think was marked Exhibit 209 previously, the IARC monograph from May of 1978.
(Whereupon, Chesney Exhibit Number 5 was marked for identification.)
BY MR. SLATER:
Q. It's probably going to take a moment because I just pulled something out of order. Look at that.
Okay. Mr. Chesney, have you ever seen -- and Chris could scroll up for you to show you what this is.
MR. SLATER: Maybe you could scroll up a little bit, show the bottom half also, or maybe make it fit the screen a little better. There we go.

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Q. And we can blow it up as you need, Mr. Chesney, whatever you need.
My first question is, have you seen this document, the IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Some N-Nitroso Compounds, Volume 17, dated in May of 1978? That's the date in the bottom left. Is this something you've seen?
A. No.
Q. And you can see it's marked with an exhibit sticker, Peng Dong ZHP 209.
Do you know who Peng Dong is?
A. The name is vaguely familiar, but I don't recall.
Q. Okay. I assume you're familiar with IARC?
A. I've heard of them. I'm not terribly familiar with them.
Q. The International Agency for Research on Cancer. That doesn't -- you're just generally familiar that they exist?
A. That's about it. I haven't had much to do with that agency over the years.

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Q. You see that this is a component of -- at the top you can see the "World Health Organization." I assume you've heard of the World Health Organization?
A. Oh, of course, yes.
Q. And what I'm going to do, if we could, is go to page 36.
MR. SLATER: And let's blow up the third full paragraph. Good job. Thank you. Maybe a little smaller. Perfect.
Q. Can you see that okay, Mr. Chesney?
A. Yes, sir, that's fine.
Q. Okay. We're looking here on page 36 of this IARC monograph, the third full paragraph, it says, "It has been known since 1865 that the reaction of dimethylamine hydrochloride with sodium nitrate at an acidic pH yields N-nitrosodimethylamine," which is NDMA.
Do you see that?
A. Yes.
Q. Is this the type of feasible

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scientific information you're talking about in terms of the ability of ZHP to have known that this reaction between the DMA that would be a degradant product of the DMF could react with the nitrous acid from the sodium nitrate and form NDMA? Is this the type of feasible scientific information you're talking about?
MR. FOX: Objection to the form. Beyond the scope of his report and the scope of his expertise, as he's testified to.
A. It's the sort of thing I would expect scientific experts with whom I would collaborate to take into consideration. By itself it is what it is, but it doesn't -- it doesn't go beyond what it says on its face. This tendency was identified a long time ago.
But it says nothing with respect to the process itself. I'd have to have somebody make that connection for me.
BY MR. SLATER:
Q. I understand. And I have a few different pieces to the puzzle that I'm planning to probably show you over the next

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few minutes.
As far as what I just showed you, this shows that IARC, an arm of the World Health Organization, published as of 1978 that it's been known since 1865 that the reaction that ultimately created the NDMA has been known to scientists. That's what this shows, right?
MR. FOX: Objection to form. Calls for speculation.
A. That's what the sentence says.
MR. SLATER: Okay. Let's go now, if we could, to page 40. And we'll blow up that last paragraph. Perfect.
BY MR. SLATER:
Q. This says in part, "Most of the chemical and physical properties of the nitrosamines described in these monographs were taken from Druckrey et al," and cites to a 1967 publication. Then it says, and this is the part I wanted to really focus on with you, "The principal techniques employed for the analysis of volatile N-nitrosamines have

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been described in a recent publication (Preussmann et al, 1978). The relative merits of high- and low-resolution mass spectrometry are discussed, since use of mass spectrometry as a confirmatory technique is particularly important."
Do you see what I just read?
A. Yes.
Q. So again, this is addressing the issue of whether or not analytical methods were available to actually detect the NDMA in 2011, 2012, and this is showing that as of 1978, it was being discussed in the World Health Organization publication that mass spectrometry was one available method.
Do you see that?
MR. FOX: Objection to the form, and incomplete recitation of the document.
BY MR. SLATER:
Q. Okay. You see that, right, Mr. Chesney?
A. I do.
Q. Okay. And again, this is the

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type of feasibly available scientific information that you were talking about earlier that you would expect ZHP's scientists to be aware of when they were doing their risk assessment, right?

MR. FOX: Objection to form.

A. It could constitute an informative data point, but it's by no means the entire picture.

MR. SLATER: Okay. Take that document down. Let's go now, Chris, if we could, to Exhibit 311, which is the publication Purification of Laboratory Chemicals.

Let me see if this has page numbers.

(Whereupon, Chesney Exhibit Number 6 was marked for identification.)

BY MR. SLATER:

Q. Okay. I've put on the screen a document titled Purification of Laboratory Chemicals, and you can see that it was marked as Exhibit 311 during the deposition of Min

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Li.

Do you see that on the screen?

A. I do.

Q. Do you know who Min Li is?

A. The name is familiar from ZHP documents, but I couldn't tell you what position she has, so that she --

Q. Or he?

A. -- as the case may be, occupies in the company.

Q. Okay. And just to be clear, you weren't provided the depositions of Peng Dong or Min Li as part of the materials you were provided, right?

A. I don't recall either of those, sir, no.

Q. Okay. And, for example, the IARC monograph I just showed you, that's not something you were provided, correct?

A. I was not.

Q. And this publication, the Purification of Laboratory Chemicals, which was used as a deposition exhibit with Min Li, that's not something you were provided

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either, correct?

A. I have not seen this document.

MR. SLATER: Chris, let's go to page 192 of this -- actually, stop don't go there yet. Let's go to the second page which has the publication dates. I just want to establish that.

Q. We can see that this has a first publication date of 1996 and reprinted in 1998, '99, and 2000.

Do you see that?

A. I do.

MR. SLATER: Let's go now to page 192. Perfect. There you go. You've got it, Chris. If you can blow up that bottom paragraph, and just read the first beginning. Just a tiny bit less because we're cutting off -- my picture cuts off. All right. Perfect. Thank you.

Q. You see that this references N-N-dimethylformamide, which is DMF.

Do you see that?

A. Yes.

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Q. And you understand that one of the changes to the manufacturing process when the zinc chloride process was created was to begin to utilize DMF. You're aware of that, right?

A. Yes.

Q. And this scientific publication, which we know was originally published in 1996 and reprinted up through 2000 on this copy that I am showing you, states that DMF "decomposes slightly at its normal boiling point to give small amounts of dimethylamine and carbon monoxide."

Do you see that?

A. Yes.

Q. And again, this would be the type of feasibly available scientific information you would expect the people at ZHP to have been aware of when they were performing the risk assessment with regard to their decision to add DMF to the manufacturing process, correct?

MR. FOX: Objection to form.

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A. It would be another data point that would have to be evaluated for its significance and context and understood fully, yes.
BY MR. SLATER:
Q. The fact that it was known in the scientific community that DMF could decompose to give off small amounts of dimethylamine is certainly something you would have expected the people at ZHP to be aware of when they were formulating and then performing a risk assessment on the zinc chloride process. You could agree with that, correct?
MR. FOX: Objection to form. Beyond the scope.
A. I would have no ability to form an independent expectation of that. That's the kind of thing I would ask the scientific expert, Is this something they ought to have known about, is this peer-reviewed research, was it -- did it have credibility, was it widely circulated. Those are all things that I would want to take into account to decide

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whether it's something that the ZHP folks ought to have known about.
It stands here as a single reference in an otherwise very lengthy document. I don't know who prominence it had in the industry at that time.
MR. SLATER: Okay. Chris, let's go to Exhibit 197, please.
MR. GEDDIS: Is there another exhibit number for that that you had too?
MR. SLATER: Possibly 14, it's the "N-N-dimethylformamide: much more than a solvent" in Tetrahedron.
MR. FOX: You're going to a different exhibit, Adam?
MR. SLATER: I am. The problem is Chris moved so quickly before, that now when he doesn't do something instantaneously we all say, What's going on?
MR. GEDDIS: What was it you said, 214?
MR. SLATER: 14, 1-4. It was

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definitely Exhibit 197 marked during Min Li's deposition.
MR. GEDDIS: 197. Found it.
(Whereupon, Chesney Exhibit Number 7 was marked for identification.)
BY MR. SLATER:
Q. On the screen we have an exhibit that was marked Exhibit 197 actually in the deposition of Peng Dong originally, I can tell you we also showed it to Min Li, and it's published in the medical journal Tetrahedron, or scientific journal I should say, and the title of this article is "N-N-Dimethylformamide: much more than a solvent?
Do you see that?
A. Yes.
Q. And this is dated in 2009. You can see it at the very top. Even though it's very small letters, it says "Tetrahedron," and the year is 2009.
A. Yes, I can see it.
Q. Great.

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MR. SLATER: Let's go now to the third page of this article, which is page 8315, please.
Q. It says in part, paragraph number 3, "Source of carbon monoxide. DMF decomposes slightly at its boiling point to afford dimethylamine and carbon monoxide, this reaction occurring even at room temperature in the presence of some acidic or basic materials. This observation has led to the use of DMF as a carbonylating agent."
Do you see that?
A. I do.
Q. Taken together with the textbook I showed you, and now I'm showing you a medical -- in a scientific journal, can you agree that, based on what I've shown you, it was at least scientifically feasible for -- and expected for ZHP to know that DMF could decompose or degrade and give off dimethylamine as part of this manufacturing process, that they at least had to take into account the possibility that that would occur?

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MR. FOX: Objection to the form. Argumentative, incomplete hypothetical.

A. I can agree that, from what you've shown me, that there are references in the scientific literature that are potentially useful data points that should be taken into account and considered in the overall scheme of things. But I'm not capable of judging them on the merits independently, so I don't know what relevance they really have.

BY MR. SLATER:

Q. What I'm just asking is, we can agree that the potential decomposition of DMF to give off dimethylamine, based on what I'm showing you, was something that you would expect ZHP to have at least been aware of as a potential chemical reaction as part of the zinc chloride process and take into account however they chose to?

MR. FOX: Objection to form.

MR. SLATER: Let me rephrase. I lost, because I was trying to finish

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the question and you objected. I'm not criticizing because I paused, but let me just ask again.

BY MR. SLATER:

Q. You would agree with me that you would expect that ZHP would have at least been aware of the potential degradation or decomposition of the DMF to give off dimethylamine, and to take that into account as something that could potentially occur during the zinc chloride process. Just limiting it to that, would you agree with me?

MR. FOX: Objection to the form. Asked and answered.

A. It's information that's out there in the scientific literature. It would have been appropriate for them to take a look at it and give it consideration.

MR. SLATER: Let's take that down now and go to Exhibit 211.

(Whereupon, Chesney Exhibit Number 8 was marked for identification.)

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BY MR. SLATER:

Q. Okay. We have on the screen an article titled Theoretical Investigation of N-Nitrosodimethylamine Formation from Nitrosation of Trimethylamine.

Do you see that?

A. Yes.

Q. And at the bottom of the first page of the article there's an exhibit sticker, Peng Dong ZHP 211. Again, I'm representing to you this was utilized in Peng Dong's deposition as well as Min Li's deposition, which we've already established you have not seen those transcripts, correct?

A. Correct.

Q. And the articles that I've shown you, these scientific articles that were used in those depositions, you haven't seen any of these, right?

A. No.

Q. Okay. Meaning I'm correct?

A. Yes.

Q. I wasn't trying to be picky, it's just sometimes the negatives on the

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double negatives won't be clear.

A. No, I have not seen this article before.

MR. SLATER: Okay. Let's, Chris, if you could just blow up the Introduction, that left column, that would be great.

Q. Okay. And let's just start out at the beginning. It says, "It is well known that N-nitrosamines are a class of undesired industrial and environmental pollutants, many of which are carcinogenic, mutagenic, and teratogenic. In particular, N-nitrosodimethylamine (NDMA), which is the simplest dialkylnitrosamine, has been demonstrated to be a potent carcinogen to various organs in animals, including liver, lung, and kidney." And I just want to stop there.

Does this comport with at least what you've learned about NDMA since you were retained in this matter, or from the literature, from the media reports you had seen before? I'm just curious if you're

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familiar with at least these types of information about NDMA.
A. The carcinogenic potential, yes. The detail involving the specific organ systems that might be at risk, no, I haven't seen much in the way of specific reference to that before.
Q. And I neglected to ask about this, but maybe I can do it real quick.
The importance of detecting genotoxic impurities as potential manufacturing process impurities, that was not a novel concept in 2011, ZHP would have known at that point that that was something they had to be on the lookout for, right?
MR. FOX: Objection to form.
A. Be on the lookout for what?
BY MR. SLATER:
Q. For genotoxic process impurities as a part of any manufacturing process?
A. There's long been a general awareness that unidentified impurities need to be characterized so you know what you're

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dealing with, and then back up and look and see what the implications are of those materials present in your product as a result of your process, and to the extent feasible to quantitate them.
Q. And with regard to genotoxic impurities which could potentially lead to cancer, it's been understood that those need to be focused on and they need to be identified and addressed, correct?
MR. FOX: Objection to form.
A. Well, if you identify either the potential or the actual occurrence of this type of impurity, then certainly it's important to understand it.
BY MR. SLATER:
Q. Looking now at the second paragraph under the Introduction, it says, "because dialkylnitrosamines are of great interest in carcinogenesis, much attention have been focused on their formation mechanism, especially from secondary amines. Consequently, NDMA is generally believed to be formed from the reactions of dimethylamine

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(DMA) and nitrosating agents, such as N2O3, N2O4 and ONCl."
And I can represent to you that N2O3 would be nitrous acid, I believe. Actually I just screwed up the whole question so I've got to ask it again.
This says, "Because dialkylnitrosamines are of great interest in carcinogenesis, much attention has been focused on their formation mechanism, especially from secondary amines. Consequently, NDMA is generally believed to be formed from the reactions of dimethylamine (DMA) and nitrosating agents, such as N2O3, N2O4, and ONCl."
Do you see what I just read?
A. Yes.
MR. SLATER: And let's just scroll up a little bit just to the authors of the article again. I want to just show -- there we go.
Q. This article was published by three authors at the College of Life Science & Bioengineering at Beijing University of

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Technology in Beijing, China, and it shows that it was -- in 2009 it was received, and published in 2010.
Do you see that?
A. Yes. Okay. I was just looking for publication date. Yes, I see that.
Q. Would you agree with me that this demonstrates that it was certainly feasible and expected for ZHP to be aware that the potential DMA that could be produced during the manufacturing process could react with the nitrous acid to form NDMA? Would you agree that this demonstrates that it's certainly something that they needed to be aware of and take into account in their risk assessment?
MR. FOX: Objection to the form. It's beyond the scope of his expertise, as he has testified repeatedly that he's not a scientific expert.
MR. SLATER: Counsel, do you want to testify?
MR. FOX: If you'd like me.

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MR. SLATER: We'll do that later. We do the lawyer testimony later.

A. This is another example of the kind of information I would need input from somebody with the appropriate expertise to fully take into consideration. I can only judge this on the merits.

BY MR. SLATER:

[redacted]

MR. FOX: Objection to the form.

MR. SLATER: Okay. I think we can take that one down.

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BY MR. SLATER:

Q. I'd like to ask you to assume that ZHP's corporate representative witnesses testified that they did not take into consideration the potential degradation or decomposition of DMF to yield DMA, nor did they take into consideration the potential reaction between DMA and nitrous acid, that they didn't even take that into consideration at all, they didn't think about it, they didn't look at the issue, they completely didn't think about that.

If my hypothetical is true, would you agree with me that that demonstrates a lack of rigor in violation of GMP based on them not even taking it into consideration and thinking about it?

MR. FOX: Objection to form.

A. I would not go that far until I had the opportunity to ask them a simple question, Why did you not, and hear what their justification is.

BY MR. SLATER:

Q. What if their justification was

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nobody knew -- rephrase.

What if their justification was, Nobody could have known that these chemical reactions could have occurred? In the face of what I've just shown you, would you agree that that would show that their evaluation fell below good manufacturing practices?

MR. FOX: Object to the form. Incomplete hypothetical.

A. I would then ask them why they took that position and what there is that's different about the chemistry of their process that leads them to conclude that.

BY MR. SLATER:

Q. What if they -- well, are you saying you would ask them why is it that you're concluding that nobody could have known about these potential chemical reactions in the face of publicly available scientific literature, including from scientists in Beijing, that you would not have known what other people had readily available to them?

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MR. FOX: Objection to the form.

BY MR. SLATER:

Q. I don't understand -- I'm just trying to understand why you would ask them that question in the face of what I've shown you.

A. I would -- no, I would expect them to know that that information was out there. But why they excluded it from consideration in their particular product would be what I'd like to hear their explanation of. I don't know if they would have such an explanation or not, but I would certainly ask them, Is there anything about your particular process that led you to believe that information such as this would not be relevant.

But a lack of awareness that it exists or even to rule it out as important, no, I would expect them to go that far at least.

Q. As a matter of GMP, right?

MR. FOX: Objection to form.

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A. Yes.
BY MR. SLATER:
Q. What if their answer to your question was, We didn't exclude it, we never even thought about it --
MR. FOX: Objection to form.
BY MR. SLATER:
Q. -- would that fall below GMP then?
MR. FOX: Objection to form. Misstates -- or incomplete hypothetical.
A. They certainly should be looking at the relevant literature to see if there's anything about what they're proposing to do in their process that poses a potential risk. So yeah, I would expect them to at least be aware of the existence of this information.
BY MR. SLATER:
Q. And if their -- rephrase.
If their response to your question, which I think you said your question would be, Well, why did you exclude

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this information from consideration, if their response was, We didn't even actively exclude it and say we're not going to consider it, we didn't even know it, because we didn't even do a research, a literature -- rephrase. Let me try to ask it clean.
If you were to ask them, Why did you decide this information didn't need to be taken into account, and they said, We didn't even make a decision about whether to take it into account, we just never even knew --
MR. FOX: Is that a question?
BY MR. SLATER:
Q. -- would I be correct that you would say, Well, your risk assessment fell below GMP because you at least should have known this information was available and made a reasoned decision as to how you were going to take it into account?
MR. FOX: Objection. Misstates testimony. It's also beyond the scope of his expertise, given that he's not a scientific expert.

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BY MR. SLATER:
Q. You can answer.
A. It's a concern I would have, but I would ask that the scientific experts I was working with resolve it on a peer-to-peer basis and give me their insight and their opinion.
Q. Well, coming back to my question, though, since you've already agreed with me that they were required to at least know about these potential chemical reactions that could occur during the process, if you then asked them, Well, why did you not perform an actual risk assessment on whether or not these reactions were going to occur or were occurring, and they said, We never even took it into account, we didn't even think about this, we never even thought about these potential reactions, if that were to be their response, would you agree that that would show that their -- the fundamental parts of their risk assessment fell below GMP because they never even made themselves aware of these potential reactions to begin with?

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MR. FOX: Objection. Beyond the scope, incomplete hypothetical, and misstates his prior testimony.
A. I'm sorry, I lost -- in all of that I lost the thread of the question. Can you restate it? I had to ask you to restate it, but please do.
MR. SLATER: Just so that I don't misstate it a little differently and get another objection that might distract you, Maureen, could you read that question back, please?
I'll ask the court reporter to read it back, and if I need to reask it I will again, but maybe this will be the quicker way to go.
(Whereupon, the reporter read back the following:
QUESTION: Well, coming back to my question, though, since you've already agreed with me that they were required to at least know about these potential chemical reactions that could occur during the process, if you

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then asked them, Well, why did you not perform an actual risk assessment on whether or not these reactions were going to occur or were occurring, and they said, We never even took it into account, we didn't even think about this, we never even thought about these potential reactions, if that were to be their response, would you agree that that would show that their -- the fundamental parts of their risk assessment fell below GMP because they never even made themselves aware of these potential reactions to begin with.)

MR. FOX: Same objection.

A. I would agree that the risk assessment would have been better had they taken that into account for sure.

BY MR. SLATER:

Q. Well, if they told you they never took it into account, that would violate GMP. You've already told me they were required to know about this scientific

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information, so if they didn't even consider it that would violate GMP, right?

MR. FOX: Objection to form. Misstates testimony.

A. I think that's taking the concept a bit far. But they certainly -- the risk assessment would certainly be improved by a thorough literature search, and if they missed something like this that was publicly available and directly involved the type of reaction that was involved in their process, then yes, it should have been taken into account. And if it wasn't, that would be a gap in the overall risk assessment.

BY MR. SLATER:

Q. It would be a gap in violation of GMP, correct?

MR. FOX: Objection to form.

A. Whether or not it's a violation of GMP I'm not been prepared to say without a more rigorous understanding of the scientific considerations here.

When you look at information like this in the literature, it may not have

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been created in an environment that duplicates adequately the environment that exists with respect to the process chemistry that you're dealing with, and there could be mitigating factors or things that would influence the production of NDMA in some way as to negate the risk. All that has to be taken into consideration before you can conclude what the impact of the lack of that information really was.

BY MR. SLATER:

Q. And what you just went through in terms of the types of questions that you might ask, you would expect that pursuant to GMP that people at ZHP would have asked themselves the same questions back at the time in 2011, right?

A. Yes.

MR. FOX: Objection to form.

A. That I can agree to. The question is whether in 2011 the technology was adequate to make that identification, and whether there was reasonable probability that they would even find anything if they looked.

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Those are the two basic questions that I would need the scientific support to answer.

BY MR. SLATER:

Q. Assuming the answer to both of those assumptions is yes, as I've asked you to assume in the hypothetical, if they didn't ask themselves those questions that you just recited for me about how you would take into account -- how to take this into account in their risk assessment, they didn't even go through that exercise, that would fall below GMP, right?

MR. FOX: Objection to form. Misstates testimony.

A. That would be a flaw in the overall risk assessment for sure, yes.

BY MR. SLATER:

Q. In violation of GMP, right?

MR. FOX: Objection to form.

A. I'm not prepared to go that far. That requires a multifaceted consideration really as to what the risk is that's presented.

If I may, GMP conceptually does

not expect everything to be done perfectly. In fact, the regulations, the finished dose form regulations actually anticipate that imperfections will occur, and what it calls for is a thorough investigation when those imperfections do occur, not that everything be absolutely perfect every time.

If that were the case, no pharmaceutical products would be produced because nobody is ever 100 percent perfect. That's been my experience.

So the question really is not whether or not the risk assessment could have been better, the question is was it sufficiently flawed to violate GMP. And it's difficult for me to take it to that level.

I can certainly agree that this information you've highlighted would have been helpful, even should have been taken into consideration. But whether the fact that it was not, if the testimony indeed states that, constitutes a violation of GMP as a further analysis, that I would not be prepared to make based on this level of

information.

BY MR. SLATER:

Q. If you were to assume that considering that information could have feasibly led to testing to see if nitrosamines were being formed, if you assume that, and that that testing would have shown NDMA was being formed, then the failure to take this into consideration in 2011 would be a GMP violation, correct?

MR. FOX: Objection to form.

A. If all that was true, yes. The problem is I've seen other information that suggests that, at least from the FDA's public statements, that suggests that that information was not -- or that technology was not up to speed until much later. Neither the regulators nor the industry at large really had that awareness.

So I question whether it was feasible in 2011. I don't know, and I would require the help of someone with the right scientific expertise to convince me of that.

If I could be convinced of that

then, sure, I could get to the point of agreeing it was a violation of GMP, but not based upon bits and pieces of the total story.

BY MR. SLATER:

Q. When you were reading the information from the FDA, were you aware that the reason why nobody had been looking for NDMA before was because the manufacturing processes for valsartan hadn't created NDMA to the FDA's knowledge before the zinc chloride process was put into effect, and that that's how this issue came to the FDA's attention?

MR. FOX: Objection to form.

BY MR. SLATER:

Q. Were you aware of that?

A. Public statements allude to the timeline on this, and the reasons why it eventually did come to light.

What I remember from that as I sit here now is that full awareness and understanding didn't really occur until sometime in the middle of 2018. So I

question whether it would have been something the company could have anticipated or known about in 2011.

Q. I read something in your report which indicated along the lines of what you've been telling me, that the FDA doesn't prescribe a one size fits all GMP approach to the manufacture of each product. I think you've been telling me that, right?

A. Yes, that's true.

Q. And I read a couple of things in your report, and I'm just going to run through them. One of the things you said is that the cGMP regulations describe what is to be accomplished, not necessarily how.

I think that's the same point, right?

A. Yes.

Q. And another thing you said is any reasonable format that achieves the desired results.

Again, that's another way of saying the same thing, right?

A. Yes.

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Q. And I think another place you said -- rephrasing.

Another part of your report on page 51 you said, As long as the approach ensures that the API meets its purported or represented purity and quality. That was another way of you saying you have to come up with an approach, it might not be the same approach someone else will have, but that's the outcome that you need to achieve, right?

MR. FOX: Objection to form.

A. Yes, I think in that -- sorry, Tom.

MR. FOX: Go ahead.

A. I believe in that case I was actually quoting an FDA compliance program to illustrate that point.

BY MR. SLATER:

Q. And that point would apply to what ZHP was doing in 2011 as part of its risk assessment, that its approach was required to ensure that the API met the purported or represented purity and quality of the API, correct?

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A. Yes.

Q. We know in retrospect that the risk assessment failed to do so, and that the API did not satisfy the represented purity and quality because it was -- it contained NDMA, correct?

MR. FOX: Objection to form. Calls for speculation.

A. I don't believe there was any specification established for NDMA at that point in time because there was no anticipation that it would be there.

BY MR. SLATER:

Q. That was due to the failure of the risk assessment to identify the potential creation of nitrosamines, correct?

MR. FOX: Objection to form.

A. In part.

BY MR. SLATER:

Q. When the valsartan was sold by ZHP, it was representing that it had a certain level of quality and purity, and listed what the ingredients and components were that were in those pills, right?

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A. I've never seen the labeling for how it was sold, nor any representations that were made to purchasers, but implicitly it would be required to comply with the law, certainly.

Q. Have you looked at the USP entries for the valsartan?

A. The monographs and the USP?

Q. Yes.

A. I don't recall that I looked at the monographs. I do have one USP citation in my list of references, but I don't think that was the valsartan monograph.

Q. You mentioned specifications before, and I think we can agree that, because we talked about it earlier, that one of the important parts of the risk assessment is to identify what are the impurities that need to be specified so that you can test to make sure they're below certain levels, right?

A. Yes.

Q. So if the risk assessment failed -- well, rephrase.

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We know the risk assessment failed to identify the potential NDMA impurity, we know that, that's why it was never part of the process validation testing, and that's why there was never any even attempt to set a specification for NDMA, right?

MR. FOX: Objection to form.

A. I think -- my understanding is that that's not the only reason.

The other reason is there were not available analytical methods that were sensitive enough at the levels that apparently this material was occurring to enable detection at that point.

BY MR. SLATER:

Q. And I think you said earlier you haven't seen Dr. Hecht's report, so you're not aware of the fact that one of the world's foremost experts regarding nitrosamines and the use of mass spectrometry has written in his report that the technical ability to identify the NDMA was absolutely available in 2011, that's not something that

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you're aware of, right?
MR. FOX: Objection to form.
Lacks foundation, argumentative.
A. I'm not aware of it, no.
BY MR. SLATER:
Q. If I am correct that it was technically feasible for ZHP to have employed technology to test for NDMA and identify the NDMA in 2011, you would agree with me based on all the information I've shown you that they should have performed that test and they should have detected the NDMA before ever marketing this product, right?
MR. FOX: Objection to form.
Asked and answered, misstates testimony.
A. That would require a series of steps; that the risk analysis would recognize that as a potential problem, that they had the available technology or acquired it or found someone to contract with to do the testing, did the testing, and identified the NDMA at the levels in which it was occurring.
And even then, you would have

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to take that quantitative information and determine whether or not that was a health risk, and if so, how severe, and to whom, and all the rest of it.
BY MR. SLATER:
Q. Well, we know what happened when the world found out there was NDMA in the valsartan, we found out that the levels that ZHP had created in its valsartan were so high that the pills couldn't be sold any longer, right?
MR. FOX: Objection to the form.
A. The levels were such that the FDA classified the recall as Class 2, which is minimal risk to health, and actually issued public advice to patients taking those tablets or capsules to continue to take the medication until they either had an alternative available, or their physician had switched their medication.
So the FDA's official advice on this was keep taking your medication until you have an alternative.

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BY MR. SLATER:
Q. Are you aware that the reason the FDA said that is because they figured it's better not to have a heart attack or stroke in the next couple weeks while you go to your doctor and get a new drug rather than stopping the pill?
MR. FOX: Objection to form.
BY MR. SLATER:
Q. Let me reask.
Are you aware that the reason the FDA said that people should keep taking the pills until they can meet with their doctor is because there was a concern that people could suffer strokes or cardiovascular episodes and die, or have massive medical harm, and that they weighed that against the risk of taking the pills for another couple weeks while they get new medication?
You understand that's why the FDA said that, right?
MR. FOX: Objection to form.
A. A couple weeks or however long it takes.

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BY MR. SLATER:
Q. Well, I mean, the FDA was making a decision, We don't want a bunch of people having strokes and dropping dead all over the place because they stopped taking their blood pressure medications while we get them onto other medications, and then the FDA -- shortly after that, this stuff was completely off the market, right?
MR. FOX: Objection to form.
A. It was off the market after the recall was conducted, yes.
BY MR. SLATER:
Q. Certainly the FDA telling people to keep taking the pills until they get an alternative blood pressure medication was not an endorsement of the safety of the valsartan, was it?
MR. FOX: Objection to form.
A. Safety is a relative concept in pharmacology. So it was a statement by the FDA that the greater good was served by patients continuing it until they could get an alternative medication.

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BY MR. SLATER:
Q. Was the FDA also concerned that because ZHP had such a massive part in the market that there could be a bunch of people left with no blood pressure drugs if they stopped taking it, and there could be a lot of people getting very, very sick and dying if they all stopped taking it right away?
MR. FOX: Objection to form.
BY MR. SLATER:
Q. Just asking if you know.
A. I don't know if they raised supply chain concerns or created a potential shortage.
Q. Let me go back to a question about the testing that you've talked about, of whether it was feasible to test.
If ZHP had actually taken into consideration the potential chemical reactions and realized that the creation of nitrosamines including NDMA was possible, and if it wasn't feasible to test for the NDMA or other nitrosamines back in 2011, wouldn't the proper thing to do at that point be to say,

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We can't move forward until we can test and confirm that these genotoxic impurities are not in this pill? Wouldn't that be what would be required if the testing didn't exist at the time?
MR. FOX: Objection to form.
Argumentative, beyond the scope.
A. If there was a concern about a substantial risk that they didn't have the feasibility to address through analytical procedures due to a lack of equipment or knowledge of the method or whatever, the usual approach is to try to find someone who can assist with that line of inquiry.
BY MR. SLATER:
Q. And I'm just going to play out what you've questioned me about to the end.
Let's assume that they -- there was no technology available to test for NDMA or other nitrosamines at that point, even though they knew this manufacturing process very well could be creating these genotoxic impurities, if that were the case -- I'm taking your hypothetical -- if that were the

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case, then they would not be able to manufacture by that process, they would have to come up with a different way to manufacture it where there wouldn't be the potential creation of a genotoxic impurity that you couldn't test for, correct?
MR. FOX: Objection to form.
A. That's a possible outcome.
BY MR. SLATER:
Q. That would be the -- I'm sorry, I missed your answer because I think you might have broken up.
A. I'm sorry, just waiting for Tom.
That -- yes, that would be a possible outcome. They could elect to hold off on the process change until that question could be answered, yes.
Q. I mean, that would be -- rephrase. That would be required -- rephrase.
At the very least, they couldn't go forward and institute that manufacturing process until they could answer

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the question of whether or not this genotoxic impurity was in the pill, right?
MR. FOX: Objection to form.
Incomplete hypothetical.
A. They should have taken that into consideration, and that's a decision that would have to be made in light of all the facts, and with the appropriate scientific expertise coming to bear.
But yes, that's a possible decision that they could have taken at that time, to not go forward.
BY MR. SLATER:
Q. It would not have been -- rephrase.
Taking your hypothetical that there was no test in existence that could have told you whether or not this genotoxic impurity was there or not, if that was the fact, it would not have been acceptable to go forward with the manufacturing process while not knowing if there was going to be this genotoxic impurity. That would not have been permitted, correct?

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MR. FOX: Objection to form. Beyond the expertise, incomplete hypothetical.
A. Again, I would agree if and only if the weight of the science argued that there was a significant risk of formation of NDMA. There are literature references which you've shown me that showed in a laboratory setting people that identified this as a potential risk that's of concern, they should consider that.
But it would take a more wholistic assessment to understand whether that was a real risk, and decide accordingly whether to proceed with that process change at that time.
BY MR. SLATER:
Q. In retrospect you would agree with me it was a real risk because it happened, right?
MR. FOX: Objection to form. Argumentative.
A. Well, I agree with you that it happened.

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BY MR. SLATER:
Q. Okay. I wanted to just establish that. If we -- if you'll assume for the moment that a reasonable scientific expert in this field would say, Yes, this would be considered a real risk that this manufacturing process could create NDMA or other genotoxic impurities, if that were the fact, and if your hypothetical was correct that no test existed that could have measured whether or not this genotoxic impurity was actually being created, under those circumstances you could not go forward and manufacture with this process, you'd have to come up with a different way to do it, right?
MR. FOX: Objection to form.
A. You should not go forward unless there's a persuasive reason to believe that the formation of these impurities would be at such a low level that it would not present a risk to human health.
MR. FOX: Break, Adam?
MR. SLATER: Sure. I was losing track of the time. It's fine.

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BY MR. SLATER:
Q. Do you want to -- I don't know what you want to do, Mr. Chesney, if you want to take a little longer, you want to eat because it's almost 1:00 o'clock, whatever you want?
A. Well, maybe a little bit longer and just grab something quick. I'm certainly not one who takes a big lunch anyway.
Q. All right. Well, you tell me, how long would you like? I'm just on my second bite of my apple so far, so I'm going to eat an entire apple for the next eight hours.
A. Okay. Well, it's about 20 minutes of 1:00, why don't we say, I don't know --
Q. I'm not trying to rush you. Make sure you give yourself a comfortable amount of time.
A. Ten minutes past 1:00 sound okay to you?
Q. That sounds really good. We'll shoot for that.

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A. All right. Fine.
THE VIDEOGRAPHER: The time is 12:38 p.m. We are off the record.
(Whereupon, a luncheon recess was taken.)

AFTERNOON SESSION

THE VIDEOGRAPHER: The time is 1:24 p.m. We are back on the record.

BY MR. SLATER:

Q. Okay. We are ready to resume, Mr. Chesney.

Question, I read your discussion of adulteration in your report, which I hope not to have a long, drawn-out discussion about it, I think I understand your points, but we may have to come back to it a little bit. But let me ask you one question maybe to help to avoid a lot of that. So here's the question.

If the zinc chloride process violated cGMP as we've discussed, if that's the case, then the valsartan API manufactured with that process would be adulterated, correct?

MR. FOX: Objection to form.

A. If it is determined that there is a GMP violation that is sufficient to establish adulteration under the FDCA.

That's a big if.

BY MR. SLATER:

Q. I understand. Nobody is saying that you've agreed to all aspects of the hypothetical I gave you, but I just wanted to understand if that's the case what the consequences were, or what the implications were.

And sort of -- okay. What I'm doing is looking at my outline to see if I can cut through a few things. Okay.

We talked a little bit about earlier about what ZHP did when they learned about the NDMA in the valsartan. I want to talk a little more about that with you, okay?

A. Okay.

Q. Let me just find in your report.

One of the things that you said in your report is the actions taken -- well, let me start over.

With regard to what ZHP did when it learned that there was NDMA in the valsartan, you say -- this is on page 40 of

your report, "The actions taken are, in my opinion, responsible steps that the FDA would expect of any company who had discovered and self-disclosed an issue with a distributed product."

I want to ask you a couple questions about that statement, okay?

A. Sure. That's on page 40. Can you tell me, I've got page 40 open on my hard copy, whereabouts are you in that?

Q. The third line from the top.

A. Oh, okay. All right. I see it, yes.

Q. When you say that those were responsible steps that the FDA would expect of any company in that situation, those steps were legally required of ZHP, correct?

MR. FOX: Objection to form. Calls for a legal conclusion.

BY MR. SLATER:

Q. I'll ask the question differently.

Based on your understanding of the applicable FDA regulations and statutes,

is it your opinion that those steps that ZHP took in June of 2018 were legally required of ZHP?

MR. FOX: Same objection.

A. No. These are not things that are covered by any specific FDA regulation or statutory requirement; they're just reasonable and proper things to do when a company has information of this sort.

But there's nothing that I'm aware of that's an affirmative duty for ZHP to have done any of these based on a specific FDA regulation or statutory requirement.

BY MR. SLATER:

Q. One of the things you told me, and it's stated in your report, is that pursuant to 21 CFR 314.81(b)(1), ZHP was required to submit a field alert report within three business days to the FDA once it had learned that there was NDMA in the valsartan, correct?

A. But that's not one of the five elements that I cite here. It begins on page 39 at the bottom.

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Q. Okay. So let's go through the five elements. Well, going back to -- I'll ask you a different question and then we'll come back to where you were.

ZHP was legally required pursuant to 21 CFR 314.81(b)(1) to submit a field alert report to the FDA within three business days of learning there was NDMA in its valsartan, correct?

A. Yes, with one slight modification, and that being that because this is under an abbreviated new drug application, the regulation that directly covers it is 314.98, but it reflects back to 314.81 for the content. So in effect, yes.

Q. Bottom line was ZHP was required to notify the FDA that there was NDMA in its valsartan within three business days of learning that, correct?

A. Yes.

Q. Once ZHP knew that the zinc chloride manufacturing process was creating NDMA as an impurity, was ZHP required to stop using that manufacturing process as a matter

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of GMP pending further evaluation?

MR. FOX: Objection to form.

A. Once again, no specific requirement for that, but that would be the reasonable thing to do.

BY MR. SLATER:

Q. Well, it's my understanding that at all times that ZHP was manufacturing valsartan with the zinc chloride process, that if it knew that NDMA was an impurity in that valsartan API, that ZHP would have had to address that situation pursuant to GMP, correct?

MR. FOX: Objection to form.

BY MR. SLATER:

Q. Starting broad right now.

A. What do you mean by "address that situation"?

Q. Well, let me ask you this question.

When ZHP first learned that there was NDMA in its valsartan API and that it was a process impurity, did GMP require that ZHP take any steps?

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MR. FOX: Objection to form. No foundation.

A. It would require that they conduct a thorough investigation to determine where that was coming from, and how to control it going forward, and what to do about it in the interim.

BY MR. SLATER:

Q. When you say how to control it in the interim, what do you mean by that?

A. Well, the steps that they took, for example, placing existing inventory on hold until the investigation was complete and the decision could be made as to what to do. Ultimately, of course, they conducted a recall, notifying customers to place a hold on valsartan API, those kinds of interim controls, while the investigation is ongoing and coming to its ultimate conclusion. Those are reasonable things to do.

None of those are prescribed specifically by GMP, but they certainly are the kinds of things that responsible companies do when in this situation.

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Q. Well, what I'm trying to understand is what GMP required based on the documents you reviewed, based on -- to the extent you have any knowledge of any internal SOPs, I'm trying to get a idea of what GMP required when ZHP first learned that there was NDMA in its valsartan API.

I think the first thing you said is it needed to do a thorough investigation to figure out why, where it's coming from, correct?

A. And also the risk. And then --

Q. I'm sorry, I wanted to go one step at a time just because --

A. Sure.

Q. I'll start over. We'll do it in small steps.

A. Okay.

Q. When ZHP first learned that there was NDMA in its valsartan API, GMP would have required ZHP to do an investigation to determine why is it there, where is it coming from, correct?

A. Yes, and the associated risk.

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Q. And to evaluate the associated risk?
A. Yes.
Q. Once ZHP understood that this was coming from the process, the manufacturing process itself, and understood that this was a genotoxic impurity that was considered to be a probable human carcinogen, what did GMP require ZHP to do once it knew that information?
MR. FOX: Objection to form.
A. If feasible, quantify the levels of the compound that were present as a result of its formation during the process, and include a health hazard assessment as to what the implications are of that level of material, once they had a clear understanding of what the levels were that were occurring, whether they were just trace levels that would perhaps have a negligible or no effect, or whether they were at levels of concern. That would be the next step.
BY MR. SLATER:
Q. You would agree with me that

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knowing what you know now, the levels were at levels that would be of concern, correct?
A. Right. And they agreed as well, that's why they conducted the recall.
Q. And again, I'm sticking with GMP right now, so I want to just make sure we're on the same page that once ZHP understood there was NDMA in the valsartan API, it needed to do a thorough investigation, determine what was the root cause, also to evaluate the potential health hazard, quantify the levels.
And then what else would have been required by GMP?
MR. FOX: Objection to form.
A. Exactly what they did here, which is for the quality unit to take appropriate action with respect to the material in their possession, and would have to evaluate whether a recall was necessary, which they did. And they placed the material on hold and notified their customers. They also notified the FDA.
///

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BY MR. SLATER:
Q. Would that also have required that they stop manufacturing for the time being?
A. It wouldn't have required that. Some companies in a situation like this where information is still developing and they're not sure where it's going to come out, if there's sufficient demand they may continue to manufacture at risk, but put any new lots manufactured also on hold.
Other companies will look at that and say no, the risk is too high, we don't want to make that investment in the cost of goods, and they'll simply cease manufacturing until they sort the matter out.
So if they continue to manufacture, they should certainly -- they would certainly not be wise to distribute any additional product made, but rather to put that on hold with the rest of it.
Q. Would there have been anything else that GMP would have required of ZHP?
MR. FOX: Objection to form.

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A. Once a final conclusion is made that the product is not in a saleable condition, then the final thing would be for the quality unit to reject the material that they still had control over and any returns they get back as a result of the recall.
Some companies in a recall situation will authorize the destruction by their consignees rather than have it all returned.
BY MR. SLATER:
Q. And your understanding is that from all the things you've seen, that ZHP first learned that there was NDMA in its valsartan in June of 2018, is that correct?
A. That's when the investigation was in its final or latter stages, and they had done some quantification, yes.
Q. Did you come to an understanding of how -- well, rephrase. Did you have an -- rephrase.
Did you review materials having to do with the interactions between Novartis and ZHP regarding the NDMA impurity in the

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valsartan which led to the disclosure?
MR. FOX: Objection to form.
A. I do recall reviewing some of the original reports, or an original report from Novartis that they had detected an unidentified impurity.
BY MR. SLATER:
Q. Did you notice that it was Novartis and a third party lab that Novartis retained that identified the NDMA before ZHP did?
A. I don't recall specific details. It's possible that I did, yes.
[redacted]

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[redacted]
in

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your report. That was not something you actually addressed in your report, correct?
A. I don't recall addressing it.
Q. Do you have any opinions as to whether -- rephrase.
I didn't see any opinions in
[redacted]
opined on, correct?
A. I don't believe I dealt with that specifically in my report.
Q. You would agree that when ZHP was receiving complaints from its customers of unknown peaks on chromatography that ZHP had certain GMP obligations in response to those complaints? We'll get to what those responsibilities were, but you would agree that that would trigger certain GMP responsibilities, correct?
MR. FOX: Objection to form. Foundation.
A. Yes, they should investigate

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those complaints for sure.
BY MR. SLATER:
Q. They would have been required by GMP to conduct a risk assessment with regard to those peaks in an effort to -- well, let me ask it differently. Maybe I won't use the word risk assessment, and you'll tell me, it could be something else closely akin.
When ZHP was -- rephrase.
When ZHP received the customer complaints of these unknown peaks in the valsartan API, GMP required ZHP to analyze and try to determine what those unknown peaks represented, correct?
MR. FOX: Objection to form.
A. When you use the word "analyze" there, can you be more specific?
BY MR. SLATER:
Q. Well, sure.
ZHP would have been required to try to learn the reason why those unknown peaks were appearing, correct?
A. Yes. And that could be through

dialogue with the complainant, review of information submitted by the complainant, review of production records, a variety of ways, sometimes including laboratory analysis of retained samples if that's appropriate. All of that has to be taken into consideration based on the details of the complaint.

Q. One of the things ZHP would have been expected to do would have been to evaluate the manufacturing process to determine whether there was the potential creation of impurities that could explain those unknown peaks, correct?

MR. FOX: Objection to form. Calls for speculation.

A. Once the manufacturing process is established and being followed, there's no requirement that they go back and reconsider something like that.

What they would need to do instead is to make sure the batch records reflect that the manufacturing process that was used for the batch that was the subject

of the complaint was followed as required by the master form of the record.

BY MR. SLATER:

Q. In terms of deciding what testing to -- rephrase.

One of the things ZHP had to do was determine what type of testing to perform to try to determine the explanation for those unknown peaks; that would have been part of what they should have done, correct?

MR. FOX: Objection to form.

A. They should have determined whether testing was even feasible or necessary, because sometimes the information that comes in from the complainant is not that you don't really need to go to testing, other times it's helpful. So it depends on the details.

BY MR. SLATER:

Q. Well, in retrospect we know that there were unknown peaks attributable to NDMA, and that certain testing would have disclosed the presence of NDMA. We know that in retrospect, right?

MR. FOX: Objection to form.

A. I'm not sure that I know that at all. First of all --

BY MR. SLATER:

Q. Was it in the materials you reviewed?

A. From the public statements by the FDA, those analytical procedures were not fully robust until a later date for one thing, you know. So I don't know what was available at the time. We've talked about these literature references and so on.

But again, this is something I would ask a subject matter expert, Was there analytical technology available that should have been used, could have been used under these circumstances to shed some light on this.

But the ordinary approach with unknown peaks is to attempt to identify them qualitatively, and then once you know that, quantitate them if that's possible with existing technology.

Q. When you say "qualitatively,"

you're talking about figuring out what they are?

A. Yeah, what is it. And then quantitatively is okay, how much is it, how much is there present, what level is it at.

Q. Well, one of the things that ZHP would have had to question was, Is there a test we can perform to identify the source of those unknown peaks. They would at least have been expected by GMP to ask themselves that question, right?

MR. FOX: Objection to form.

A. What I have seen the scientists do is look at the unknown peaks, look where they're alluding, evaluate the size and occurrence of them, and attempt to infer from that what might be going on.

If additional testing is necessary, then they do that, but I'm not the one to make that call.

BY MR. SLATER:

Q. I read somewhere, and I don't remember if it was in your report or in some of the ICH documents, that risk assessment is

not a static process, it's a process that continues through the lifecycle of the drug's production and manufacture, is that correct?
A. I would agree with that statement, yes.
Q. So when the unknown peaks were brought to the attention of ZHP, one of the things that would have been prudent for them to do would have been to go back to their risk assessment to determine whether it was adequate to make sure they hadn't missed something that could explain those unknown peaks. That would have been a prudent step, right?
MR. FOX: Objection to form.
Calls for speculation.
A. I don't know if they did that or not, but they certainly could have.
BY MR. SLATER:
Q. It would have been prudent for them to do so, correct?
MR. FOX: Objection to form.
A. Yes.
///

BY MR. SLATER:
Q. And if it was scientifically feasible for ZHP to have evaluated the manufacturing process, gone through the chemical reactions that could have been occurring, and identify that potentially nitrosamines were being created, and if it was technically feasible to perform a test like mass spectrometry to determine whether these were nitrosamines causing these unknown peaks, if both of those ifs -- if the answer is yes to both of those, then that would have been expected by ZHP, that would have been expected by GMP, correct?
MR. FOX: Objection to form.
Incomplete hypothetical.
A. That's the sort of question I would turn to a subject matter expert to help formulate.
BY MR. SLATER:
Q. I'm asking you to assume the answer is yes, it would have been scientifically feasible to figure out that these reactions could have led to the

creation of nitrosamines, and I'm asking you to assume that testing, including mass spectrometry, was available to test to see if this was a nitrosamine peak, if the answer to both of those is yes, then GMP would have required ZHP to do so when those unknown peaks were reported, correct?
MR. FOX: Objection to form.
A. There's a lot of ifs in that hypothetical.
BY MR. SLATER:
Q. Is the answer yes?
A. The answer would be yes, if the answer to all the ifs you just posed was also yes.
Q. So again, this comes back to the importance of identification of the potential impurity being the trigger to many of these cGMP functions, correct?
MR. FOX: Objection to form.
A. Yes.
BY MR. SLATER:
Q. Would you agree that as soon as ZHP had internally determined that those

unknown peaks could be due to the formation of a nitrosamine as a result of the manufacturing process, that ZHP was obligated to tell the complaining customers that based on their analysis of the manufacturing process, one explanation could be nitrosamines?
MR. FOX: Objection to form.
Calls for speculation, incomplete hypothetical.
A. There's no requirement for them to notify the complainant at that stage of the game. They're in the middle of an investigation. They have a hypothesis formed, as you've described it, they're putting a hypothesis to the test, so their main investigation, that would probably be a premature point at the time.
BY MR. SLATER:
Q. Once ZHP actually tested its hypothesis and confirmed that there was NDMA forming in the valsartan as a result of the manufacturing process, at that point was ZHP required to notify its customers?

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MR. FOX: Objection to form.
A. Required, no. Prudent, yes.
BY MR. SLATER:
Q. How about a customer that had complained and said, Please tell us what these unknown peaks represent, was ZHP required to tell those complaining customers once ZHP knew it was NDMA, that yes, those peaks were due to NDMA?
MR. FOX: Objection to form.
No foundation.
A. Not required by GMP, but again, the sort of thing that prudent companies do, and in fact ZHP did in June of 2018.
BY MR. SLATER:
Q. If ZHP knew that there was NDMA in its valsartan API and continued to sell the API and didn't tell any of its customers and didn't tell the FDA, that would be inexcusable, correct?
MR. FOX: Objection to form.
No foundation, argumentative, beyond the scope.
A. Use of the word "inexcusable"

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is a little inflammatory. I think if they had knowledge that a product posed a danger to health and didn't do anything about it, that would certainly be inappropriate, and they could potentially be in violation of the Act for other reasons other than GMP as well.
BY MR. SLATER:
Q. What could they potentially be in violation of under the Act, aside from GMP?
A. If --
MR. FOX: Objection to the form. Calls for a legal conclusion.
BY MR. SLATER:
Q. You can answer.
A. Okay. If they are aware that a product contains a contaminant that poses an actual or potential danger to health, and tell no one and continue to ship it anyway, that could be construed later, after evaluation of all the facts, as having shipped a contaminated and, therefore, adulterated product in interstate commerce.
Q. What are the consequences for

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that?
MR. FOX: Objection to form.
Calls for speculation.
A. Well, any of a number of consequences. It would depend on a variety of factors.
A product can be seized. If it's domestic US channels of distribution, FDA can move for that.
FDA can seek an injunction to cause a company to cease and desist violative conduct.
They can deal with it as they did in this case with a warning letter, which is a lesser way of handling it.
There are a number of other possibilities, depending on the circumstances. And whether it's in domestic commerce or coming in from abroad would change the equation as well.
BY MR. SLATER:
Q. Well, here we're talking about API that was coming in from China.
A. Right.

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Q. If it turned out that ZHP knew that its zinc chloride manufacturing process was creating NDMA in the API, and ZHP despite that knowledge continued to sell the API and not inform any of its customers or any regulatory authorities and kept that knowledge secret and did so for months, that would be a violation, I would assume, of the Food, Drug, Cosmetic Act, correct?
MR. FOX: Objection.
Hypothetical, no foundation.
MR. SLATER: You know what, Counsel, you can have your -- you have your standing objection, because you give it to every question, I'm not going to make you keep saying it. I want to just get through this.
MR. FOX: It's beyond the scope of his opinion.
MR. SLATER: I'm not so sure it is.
A. Okay. Once again let's be clear on what the question is, Mr. Slater.
MR. SLATER: I'm going to ask

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Maureen, if you could read it back. It worked well the first time, so try the second time.

(Whereupon, the reporter read back the following:

QUESTION: If it turned out that ZHP knew that its zinc chloride manufacturing process was creating NDMA in the API, and ZHP despite that knowledge continued to sell the API and not inform any of its customers or any regulatory authorities and kept that knowledge secret and did so for months, that would be a violation, I would assume, of the Food, Drug, Cosmetic Act, correct.)

A. One thing that's missing from the fact set that you put forth is how much of the NDMA is present, whether it's at miniscule trace amounts or amounts that could potentially pose a hazard to health, and that would be necessary for me to give an opinion.

I would also need to know once the amounts were quantified what the medical

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opinion is in terms of the health hazard that would be necessary. Because if something is present at very minuscule trace amounts that pose no risk whatsoever, then that could result in a different answer.

BY MR. SLATER:

Q. Do you know the amounts that were found in ZHP's API? Did you have a chance to see that?

A. I have.

Q. Those amounts.

MR. FOX: Object to form.

A. Yeah, those amounts are concerning. And again, there are a lot -- a string of ifs in a row here. If this was going on, if they were fully aware of it, if they didn't notify the FDA, if they didn't notify their customers, if they continued to sell it, and so on, then yes, that could be construed as a violation of the Food, Drug & Cosmetic Act. I don't want to give a legal opinion here.

The fact is, as my report relates, that's not what they did in 2018.

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BY MR. SLATER:

Q. When you say that could be a violation of the Food, Drug, Cosmetic Act, could that be something that could rise to the level of being criminal?

MR. FOX: Objection to the form. You're asking him for a legal opinion.

MR. SLATER: He's your expert who cited to regulations all over the report. I think he's competent to talk about the legal implications of the conduct of your client.

MR. FOX: And I think he did that in the report. You have my objection.

MR. SLATER: I appreciate it.

BY MR. SLATER:

Q. You can answer.

A. Any decision to go forward with a criminal prosecution would go even beyond the scientific multidisciplinary process that I mentioned. This is hence my reluctance.

[redacted]

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[redacted]

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[redacted]

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[redacted]

Q. Okay.

MR. SLATER: Let's go to the next page, please, Chris.

MR. FOX: Is there a date on this, Adam?

MR. SLATER: Is there a date on this. I believe I can get that for you. I don't remember that off the top of my head.

MR. FOX: Okay.

MR. SLATER: But we can get that and we'll certainly make a record of it. It was used in a prior deposition, so it's certainly been identified in the metadata.

BY MR. SLATER:

[redacted]

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[redacted]

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[redacted]

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[redacted]

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[redacted]
another exhibit which will be, I believe, 296.

(Whereupon, Chesney Exhibit Number 10 was marked for identification.)

MR. SLATER: Chris, I want the translated version of this, not the Chinese version of the e-mail.

A. Can we pause on that PowerPoint for just a moment?

BY MR. SLATER:

Q. Sure, we can go back to it.

A. I just have a question.

[redacted]

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[redacted]

A. From my experience when you go from Chinese to English, sometimes things don't come across quite the same way.

Q. Fair enough.

A. I've dealt with Chinese companies in the past, and sometimes things are a little hard to follow in the translated version.

Q. No problem.

Let's go back to Exhibit 296 now.

Now, I'm showing you an e-mail marked as ZHP 296 which was sent by Jinsheng Lin, Ph.D who we just read about in that CEMAT PowerPoint. And do you see his name there at the top?

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A. Yes.

Q. And it was sent to a number of people, Jucai Ge, Tianpei Huang, Wangwei Chen, Wenquan Zhu, Wenbin Chen, Mr. Li, Peng Dong, Lihong Lin, Yanfeng Liu, Peng Wang, and Wenling Zhang.

Do you see that?

A. I do.

Q. And the date of this e-mail is July 27, 2017. Do you see that towards the top of the e-mail?

A. Yes.

Q. And what I want to do is go through first, this is -- the first person it's sent -- rephrase.

It's addressed to Ms. Ge. As you can see, it says, "Ms. Ge: According to the results of our telephone communication with the Technology Department at Chuannan Plant today," and then it talks about "the incomplete quenching of sodium azide caused by the separate treatment of irbesartan sodium azide wastewater," and it goes into that area, it discusses that.

Do you see that?
A. Yes.
Q. Okay. What I would like now to do is go to -- now, looking at the bottom of that paragraph, Dr. Lin points out, "However, after the improvement, there is an unknown impurity of about 0.544 percent at 26 minutes in the crude irbesartan, and it is the largest impurity in the irbesartan crude product."
Do you see that?
A. Yes.
[redacted]
MR. SLATER: Let's go now to the next page, please, Chris, the top of the second page.

Q. At the top of the next page Dr. Lin states, "Through the secondary mass spectrometry analysis, it can be inferred that the extra NO substituent is in the cyclic compound fragment, and it is very likely that it is an N-NO" -- which would be an N-nitroso -- "compound; it is similar to the N-nitrosodimethylamine that occurs in valsartan when quenched with sodium nitrite, and its structure is very toxic." Then it says, "Its possible formation route is shown as follows:"
Do you see what I just read?
A. Yes.
Q. Were you aware before right now that at least as of July 27, 2017, ZHP knew internally that there was NDMA in valsartan, and that the mechanism that was creating it occurred when the valsartan was quenched with sodium nitrite during the manufacturing process?
MR. FOX: Objection to the form. Misstates the document.
A. I can't conclude that based on

what you've read up to this point in time.
BY MR. SLATER:
Q. Okay. This e-mail is dated July 27, 2017.
A. No, the date is not in question. But I can't conclude from what I've heard so far that this suggests that this material is actually in finished valsartan.
It talks about being in crude irbesartan, and at some stage of production in valsartan. I have no idea how much more synthesis or purification either of those compounds are supposed to go through as they're being manufactured and whether that would remediate this or not.
That's exactly the kind of scientific analysis that I would defer to others and would require collaboration on.
Q. Okay. I hadn't asked a question at that point, but I appreciate you telling me where you wanted to take this. But let me go back now to what I want to ask you.

This e-mail is dated July 27, 2017. It's written by Jinsheng Lin, who we [redacted]
We went through that just a few moments ago, correct?
A. Yes.
[redacted]

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[redacted].

Q. What I'm asking you is -- so we've established that. Now let's go to my next question.

In this e-mail Dr. Lin, whose responsible was to understand and discover such root causes, states that what was being seen in the irbesartan "is similar to the NDMA that occurs in valsartan when it's quenched with sodium nitrite."

Do you see that? Just asking if you see those words.

A. I do.

[redacted]

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[redacted]

Q. And in this e-mail, Dr. Lin compares what is being seen in this irbesartan that they're experimenting with and says that what they're seeing is similar to the NDMA that occurs in valsartan when quenched with sodium nitrite. He's stating a comparison to what -- according to the words on this page -- what he knows to occur in the valsartan when it's quenched with sodium nitrite, which you'll agree with me is a true statement because that was the ultimate root cause ultimately disclosed to the world, correct?

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MR. FOX: Objection to form. The document speaks for itself.

A. I'm still not certain about the timeline here, but I mean, it says what it says. So certainly I'm not quarreling with the fact that the words are there.

But whether that aligns to what the other documents I reviewed say in terms of when that determination was made, my memory is the final determination that they based the recall on was not made until 2018, which would have been approximately a year more or less after this was done.

So I'm not sure when the gentleman makes this statement whether he's basing that on a final conclusion, a speculation, a work in progress, or what that is. It says what it says.

But beyond that, I don't know.

BY MR. SLATER:

Q. Well, you know from the materials you were provided that what he says here is the root cause for the creation of NDMA.

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A. Was eventually determined to be.

Q. Okay. And he was speaking to the root cause in July of 2017. That's what it says right here, right?

MR. FOX: Objection to form. The document speaks for itself. Stop trying to put words in his mouth.

BY MR. SLATER:

Q. That's correct, right, Mr. Chesney?

A. It says what it says.

Q. You were not shown this document or told about this e-mail by the people who retained you, is that correct?

A. This is the first time I've seen it.

Q. And you saw the list of people on the first page that this was sent to. So this was not one person hoarding this information; it was shared with multiple people within the company. I showed you that, correct?

A. You showed me the list that it

was supposedly sent to, yes.
Q. If ZHP knew, as reflected in this document, that there was NDMA in valsartan as of July 2017, all the things that you said that ZHP was required to do in June of 2018, you would say all those things were required to be done as of July 2017 when ZHP knew this, correct?
MR. FOX: Objection to the form. Calls for speculation.
A. What we have in this document is a side statement in one sentence to this information. I don't know what's behind that, what the writer meant, particularly in Chinese -- I assume this was originally written in Chinese -- when he crafted this statement, what -- how deep his knowledge or understanding of that was or whether that was a speculative or off-the-cuff remark.
It's really very difficult to make any definitive conclusion from this about what the company actually knew and how many people knew it in 2017.
He's making an -- I guess you'd

call it at minimum an allegation, or a suggestion maybe is a better way to put it, that this is the case. What the facts are behind that and how well-known they are, I have no idea.
BY MR. SLATER:
Q. With all due respect, that's not what I asked you, to give me every reason that you could come up with why someone might want to try to undercut the statement. That's not what I asked you. So let's go back to my question.
If, as stated in this document, ZHP knew that there was NDMA in the valsartan and it was a process impurity that was being created when the sodium nitrite quenching step occurred as part of the zinc chloride process, then everything you said ZHP was required to do in June of 2018 would be transferred back to July of 2017, or whenever earlier date they knew this, and all those things would have been required at that time, correct?
MR. FOX: Objection to the

form. Lack of foundation, incomplete hypothetical, calls for speculation.
A. If they knew it, yes.
BY MR. SLATER:
Q. If they knew as of at least July 27th -- rephrase.
If ZHP knew at least as of July 27, 2017 that there was NDMA in the valsartan, and kept that secret and didn't tell any customers or any regulators until Novartis came to them and forced them to disclose this information in June of 2018, that would be a violation of the Food, Drug and Cosmetic Act, correct?
MR. FOX: Objection to form.
A. It would if it was offered for importation into the United States, yes.
BY MR. SLATER:
Q. We know that ZHP was selling its valsartan with NDMA in it right through until the recall occurred in June or July of 2018, right?
MR. FOX: Objection to the form.

A. I haven't looked at their sales and distribution records. I know only that they had product on the market when they conducted the recall, or there wouldn't have been anything to recall.
MR. FOX: Adam, is there a reason why you're not appearing on any of these screens?
MR. SLATER: Is there a reason I'm not appearing? I'm looking right at myself.
MR. FOX: Okay.
MR. SLATER: I'm right below Mr. Chesney, where I belong.
THE WITNESS: I can see him.
MR. SLATER: He's sitting right on my -- he's got his feet right on my shoulders right now.
A. Actually you're at the bottom on my list, but I can see you.
MR. SLATER: I'm in here.
MR. FOX: Okay. I found you.
BY MR. SLATER:
Q. Okay. If, in fact, ZHP knew at

least as of July 27, 2017 that there was NDMA in the valsartan and didn't tell its customers and didn't tell any regulatory authorities and just continued to sell the product, that would be a very serious violation of the Food, Drug and Cosmetic Act, correct?

MR. FOX: Objection to form. Argumentative, lacks foundation.

A. It would be of great concern if indeed that's true, but I don't know that it is.

BY MR. SLATER:

Q. In terms of your ability to form an opinion in this case, this is the type of information you would have expected to have been provided when you were provided materials by counsel, correct?

MR. FOX: Objection to the form.

A. If I had been provided this information, it would have raised certain questions in my mind. I would have referred those to scientific subject matter experts,

but I would have taken note of it.

BY MR. SLATER:

Q. Let's go down a little further in this e-mail.

After the pictures of the potential formation route of the nitrosamine impurity in the irbesartan, the second paragraph under that says, "If it is confirmed as the above speculated structure, then its toxicity will be very strong, and there will be an extremely high GMP risk. This is a common problem in the production and synthesis of sartan APIs. It is recommended to improve other quenching processes (such as NaClO) along with the optimization of the valsartan sodium azide quenching process."

Do you see that?

A. I do.

Q. So this provides further information about the depth of understanding by ZHP as of July 2017, because this shows that they knew that this is a common problem in the production and synthesis of sartan

APIs. That's additional important information, right?

MR. FOX: Objection to the form.

A. It also characterizes the findings up above as not confirmed and speculative.

BY MR. SLATER:

Q. The speculated structure is talking about what was being seen in the irbesartan, which was something they were working on to try to work on that process to manufacture it. They're not speculating about there being NDMA in valsartan; that's not stated as speculative at all, correct?

MR. FOX: Objection to form. The document speaks for itself.

MR. SLATER: Counsel, you have to stop, with all due respect, making a document speaks for itself objection. I would appreciate it if it would stop. I know you're new to this litigation, but the Special Master has instructed that that

objection should not be made.

You don't have to take my word for it, I'm just trying to help.

BY MR. SLATER:

Q. Can you answer the question, please?

A. I'm just taking a minute to read it here.

(Witness reviewing document.)

A. I'm having trouble from these isolated paragraphs here making a link back to valsartan, frankly. I hear what you're saying, but I'm not able to get there based on what it says right here.

Q. I'll ask you a different question then.

You see the sentence that says, "This is a common problem in the production and synthesis of sartan APIs"? Do you see that sentence?

A. I do.

Q. That's not phrased as something he's speculating about; that's being stated as fact in this e-mail. That's how it reads,

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right?
A. Yes.
MR. FOX: Objection to the form.
BY MR. SLATER:
Q. Did you say yes?
A. Yes.
Q. And we know in retrospect that this was a common problem in the production and synthesis of sartan APIs, which is why ultimately it turned out that other manufacturing processes were implicated in irbesartan and losartan, that there were recalls of those drugs as well. That was ultimately learned, correct?
MR. FOX: Objection to form.
A. Yes.
BY MR. SLATER:
Q. And in fact, Dr. Lin makes the responsible recommendation to improve the other quenching processes along with the optimization of the valsartan sodium azide quenching process. That's the responsible thing to say when you realize that your

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manufacturing process is creating a genotoxic impurity, in this case NDMA, correct?
MR. FOX: Objection to the form.
A. You're talking about the last paragraph here.
Okay. I'm sorry, but I was catching up with you by reading this in a little more depth, could you either repeat the question or have it read back to me, please?
BY MR. SLATER:
Q. Sure.
It was responsible for Dr. Lin to state, as he did, that he was recommending that they improve the other quenching processes such as NaCIO, along with the optimization of the valsartan sodium azide quenching process, because of the fact that, as he stated, this is a common problem in the production and synthesis of sartan APIs. That's a responsible recommendation, right?
A. Yes, it is.
Q. In the last paragraph he

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states, "I've also attached a patent of a 2013 sodium azide NaCIO quenching method by Zhejiang Second Pharma Co., Limited. They proposed that the use of NaNO2 quenching will result in the formation of N-NO impurities," which is N-nitroso impurities. "At the same time, they used ZHP's crude Valsartan in their LC-MS test" -- that would be liquid chromatography-mass spectrometry -- "and detected this impurity. This indicates that other companies have paid attention to the quality problem very early on. So leaders please pay attention to this issue."
Do you see that paragraph I just read?
A. Yes.
Q. Dr. Lin's statement to these other executives -- rephrase.
Dr. Lin's statement that other companies are aware of this quality problem, and giving an example going back to 2013, that's significant, isn't it?
MR. FOX: Objection to form.
A. It's my understanding that at

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that point in time other companies had not conducted recalls or taken any market action with respect to the issue, so it sounds to me like it was something the industry was in the process of coming to an understanding of at that time.
BY MR. SLATER:
Q. Most important -- rephrase.
At the very end he says, "So leaders please pay attention to this issue." That is a very responsible thing to say in this e-mail, alerting the others that receive this e-mail of this situation with the creation of NDMA and the fact that it's a common problem in the production and synthesis of sartan APIs. It's responsible for him to tell the leaders in his company to take note of this situation, right?
A. Yes.
MR. FOX: Objection to form.
BY MR. SLATER:
Q. And in fact, the leaders of the company, right up to the highest executive, would have the ultimate responsibility for

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this quality problem, right?
MR. FOX: Objection to form.
A. Yes.
BY MR. SLATER:
Q. And you've actually written on that subject and published on that subject, correct?
A. Yes.
Q. You would agree with me as a matter of GMP that the information in this e-mail could not be ignored; it needed to be aggressively evaluated by the so-called, quote-unquote, leaders as soon as it was brought to their attention, right?
MR. FOX: Objection to form.
A. Yes.
BY MR. SLATER:
Q. And we know in retrospect that what Dr. Lin said about the valsartan quenching creating the NDMA and this being a common problem in the production and synthesis of sartan APIs, we know in retrospect he was 100 percent correct about those statements. You've seen that in the

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materials you've reviewed for this case, right?
MR. FOX: Objection to form. Argumentative.
A. Ultimately that information was developed, yes.
BY MR. SLATER:
Q. Are you stunned to see this e-mail, and to see that this information was being circulated within ZHP as of July 2017? Because you said it's the first time you've become aware of that.
MR. FOX: Objection to form.
BY MR. SLATER:
Q. Are you stunned, shocked, surprised? What word would you put on it?
A. I wouldn't say stunned. It sounds to me like an appropriate notification based on some information that is outlined in the e-mail.
It's a few months before -- actually about -- let's see here, about 10 or 11 months before the recall, and these things are -- complex scientific issues like this

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don't get resolved overnight.
I don't know what was done about this, whether this was a triggering point for further work that culminated in the notification to FDA and the recall, or what.
But it certainly is responsible for Dr. Lin to have made this notification, and it looks like he made it to the right people.
Q. We know, again in retrospect, that what Dr. Lin said is accurate, and we know that he must have had a way to know it because -- well, rephrase.
You're certainly not taking the position that he just came up with this out

MR. FOX: Objection.
MR. SLATER: Chris, let's go to

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the article in the Quality Management Essentials publication that I just mentioned a moment ago indirectly, please.
And I'm not sure what exhibit number would this be for the record, if anybody knows.
MR. GEDDIS: That would be Exhibit 5.
(Whereupon, Chesney Exhibit Number 11 was marked for identification.)
MR. FOX: Which exhibit is this on the screen?
MR. SLATER: I think I was just told Exhibit 5.
MR. FOX: So this has not been used before.
MR. SLATER: This has not been used before.
BY MR. SLATER:
Q. And you recognize this publication, Quality Management Essentials, Expert Advice on Building a Compliant System?

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You recognize this publication from 2018, correct?
A. I don't recognize the artwork, but I recognize the title, yes.
Q. And if we go to the third page, the Table of Contents, we can see that you actually wrote an article that was included in this publication titled Executive Responsibility for Quality, correct?
A. Yes, that's correct.
Q. Let's go to your article which comes right after that. And this is titled -- rephrase.
Your article is titled Executive Responsibility for Quality, and I want to go to the section titled Importance of Quality just below that.
MR. SLATER: Chris, could you make it a little bigger, please?
Perfect.
A. That's fine.
Q. This says, "Importance of Quality.
"Executive commitment to

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quality in the pharmaceutical industry is critical, not only to ensure continuing profitability of the company, but also for the safety and well-being of patients and to meet the needs of healthcare providers who prescribe and use pharmaceutical products every day."
That's what you wrote, correct?
A. Yes.
Q. The primary concern has to always be the safety and well-being of patients, right?
A. Yes.
Q. It would never be acceptable for ZHP or any other company to place profits over safety, right?
MR. FOX: Objection to form.
A. I agree with that.
BY MR. SLATER:
Q. For example, if it turned out that ZHP was making so much money with the zinc chloride process to manufacture valsartan API that they chose to keep secret from its customers and the regulatory

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authorities that they knew there was NDMA in the valsartan because they were so enamored with the profits they were making and put that ahead of the safety of people using those pills, that would be reprehensible, right?
MR. FOX: Objection to the form. Argumentative, no foundation, beyond the scope of his expertise.
A. It would be of great concern, yes.
BY MR. SLATER:
Q. It would be reprehensible, right?
MR. FOX: Objection. Same objection.
A. That's a value judgment word. I prefer more precise terminology. But it would not be a good thing.
BY MR. SLATER:
Q. Going down a little further to the fourth full paragraph under Importance of Quality, there's a paragraph that says, "For these reasons, quality assurance (QA) and GMP

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compliance may be viewed differently in the pharmaceutical industry than in those industries where a reputation for high quality drives sales. Quality assurance may be viewed as a 'cost of doing business' or an internal 'police department' issuing directives that delay or prevent product release. That viewpoint can result in a low priority being assigned to quality operations and resourcing, which can lead in turn to quality problems, regulatory difficulties, unnecessary expense, adverse publicity, lawsuits and investor disappointment. All these consequences are preventable if executive managers understand the importance of the quality assurance function and treat it as a critical business operation just like other critical areas, such as strategic planning, financial management and others."
That's what you wrote because you believed it to be true, correct?
A. Yes, sir.
Q. Let's go now to the next page. There's a heading that says Regulatory

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Considerations. And you wrote, "In addition to the business benefits, health regulatory agencies around the world both require and expect top management to support a strong quality assurance function for their companies."

Top management would include, for example, the chairman of ZHP, Mr. Baohua Chen; he would fall within the context of top management, right?

A. Yes.

MR. FOX: Objection.

I'm sorry, Adam, I didn't hear the name that you mentioned.

MR. SLATER: I said Baohua Chen. Mr. Baohua Chen.

BY MR. SLATER:

Q. You then go through, after introducing this section, a couple of cases from the US Supreme Court that addressed the executive responsibility for certain regulatory violations, correct?

A. Yes.

Q. The first case you talk about

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is US versus Dotterweich where you say that "Mr. Dotterweich's company, Buffalo Pharmacal, was inspected by the FDA, resulting in direct adulteration and misbranding findings. The FDA criminally prosecuted Mr. Dotterweich and the company, charging that as president, he was ultimately responsible for the company's actions and therefore should be found guilty of violating the law."

And you put that in the article because you found that to be a significant case and a significant cautionary tale, correct?

A. Yes.

Q. You said, "Following a District Court case and subsequent appeal, the Supreme Court ruled on his case and concluded that as president, he could be held responsible for the acts of the corporation even though he did not know of the violations and did not intend for them to occur. This has become known in the US as the Doctrine of Strict Liability, or 'Responsible Corporate Officer'

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doctrine. It applies to those who, in the words of the Court, '...stand in a responsible relationship to the acts of the corporation.'"

And again, you stated this because you're cautioning the executives in pharmaceutical companies to take their quality obligations very seriously, right?

A. Yes.

Q. You then talk about the Park case, US v. Park, and you say in part, "Like Mr. Dotterweich, Mr. Park defended himself by claiming that he was not involved in the conduct that violated the law and that he had delegated authority to 'dependable subordinates' he trusted to do the right thing."

And a little further down you actually quote from the majority opinion from the Supreme Court stating, "The Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will ensure that violations will not

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occur.

"The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding and even onerous, but they are no more stringent than the public has the right to expect. We are satisfied that the Act imposes the highest standard of care and permits conviction of responsible corporate officials, who in light of this standard of care, have the power to prevent or correct violations."

And you quoted that language because you felt it to be, again, not only a cautionary tale, but right on point to get the attention of executives, correct?

A. That's right.

Q. When you talk about demanding and even onerous obligations and the highest standard of care, those statements would apply to ZHP, too, right, and their executives, correct?

MR. FOX: Objection to form. Calls for conclusion.

A. In my opinion they apply to anyone in the FDA-regulated industries.
BY MR. SLATER:
Q. Looking now on page 5, if you could. Towards the bottom, you provide at the bottom, you say, "some general suggestions that apply to all companies in this industry, regardless of size or complexity."
And number 1, you say, "Executive managers must recognize the criticality of a strong quality assurance organization and quality system to patient safety and to the company's business success."
And that's an important foundational point, right, that QA has to be prioritized? Right?
A. Yes.
Q. Looking at number 2, "Quality management must be seen as similar to other critical business management activities executives participate in, such as strategic planning, budget management, succession

planning and other areas."
And then number 3, you say, "Executive management teams must support their QA organization with authority and resources that are equal to the responsibility they have."
And then you say a little further down that the structures within the company "must assure that the quality unit can make decisions without undue influence from other organizational components and avoid conflict of interest."
Again, these are all what you believe to be very important points for any responsible company to follow, correct?
A. Yes, that's correct.
Q. Number 4, you wrote, "Executive management must establish a strong quality policy that makes it clear the company is committed to consistently producing high-quality products that perform clinically as intended. Day-to-day statements and actions of top level executives must demonstrate that this commitment is real, not

just words on paper."
I wanted to ask you about the "words on paper" part, because that jumped out to me when I read this.
That's an important point to you, that it's not enough just to put these policies in writing, but you actually have to be committed to following through with them and taking these obligations seriously, right?
MR. FOX: Objection to form.
A. Yes.
BY MR. SLATER:
Q. Number 5, you say, "As with other management responsibilities, executive teams must be kept aware of the performance of the quality system and of any emerging problems that are being dealt with."
MR. FOX: Is that a question?
BY MR. SLATER:
Q. That's another important point that you felt needed to be communicated to executive management in pharmaceutical companies, correct?

A. Yes.
Q. And I think overall what I'm hearing here is that the top level management has to essentially make very clear to everyone in the company that quality is very important, safety is very important, and it should never be minimized and never be put aside for considerations of profit, correct?
MR. FOX: Objection to form.
A. Yes, correct.
BY MR. SLATER:
Q. Did you read in the FDA documents where Jung Du told the FDA investigator that the zinc chloride process allowed them to increase their yield and lower their cost, and to thus dominate the world market for valsartan?
Did you see that statement?
A. Yes, I did.
Q. That's a concerning statement to you, isn't it?
MR. FOX: Objection to form. Calls for speculation.
A. Well, it's a statement that's

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not unreasonable to make if there are benefits to -- you know, enhancing the process for those reasons, that's fine, as long as these other principles we've been discussing are given proper consideration. There's nothing wrong with improving a process, there's nothing wrong with being profitable for that matter, provided that these other principles are respected.

BY MR. SLATER:

Q. With regard to the e-mail I showed you from July of 2017, matched up against what Jung Du told the FDA investigator, does that cause you some concern about whether or not ZHP kept secret its knowledge that there was NDMA in their valsartan because they were making so much money?

MR. FOX: Objection. Calls for speculation.

A. I don't see any connection on the surface of it. I think that e-mail by itself certainly is the type of upward communication that I'm talking about here

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that should be made on a regular basis. But there are many questions about what was then done about it, how complete and accurate its foundation was and all that.

But that's exactly the sort of thing that should be -- questions that should be asked when someone like Dr. Lin raises that kind of an issue to upper management.

BY MR. SLATER:

Q. If a decision was made not to investigate in any detail this issue and not to disclose it in any reports or to anybody because of the profits that were being made with this valsartan API, that would be a very, very serious problem, right?

MR. FOX: Objection to form. Calls for speculation, argumentative.

A. I've certainly seen no evidence that that was the case. But if it was the case, then yes, it would be of concern.

BY MR. SLATER:

Q. Going now to the Summary at the -- one second actually.

Looking at the next section, it

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says, "Common Mistakes Executive Teams Make," number 3 you wrote, "Emphasizing production quotas and market demands to the extent that quality problems are overlooked or regarded as unimportant - worst case, deliberate coverup of known quality problems through falsification of records." I'm going to stop there.

When you say, "worst case, deliberate coverup of known quality problems through falsification of records," you're saying that would be as bad as it gets pretty much, right?

A. Yes.

Q. Are you aware that -- well, rephrase.

To the extent that ZHP knew there was NDMA in its valsartan as of July 2017 or earlier, yet continued to represent to customers and regulators and the world that what they were selling was valsartan of the expected quality and the expected purity and didn't disclose the NDMA deliberately, that would be as bad as it gets, right?

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MR. FOX: Objection to form.

BY MR. SLATER:

Q. If that happened, that's as bad as it gets, right?

MR. FOX: Objection to form. Lacks foundation, calls for speculation.

A. I don't see enough in the July 2017 e-mail to enable me to conclude with finality that the premise of your question is accurate.

There certainly are some concerns expressed there that are appropriate to express, they're being expressed to the right people. But full background and all the facts would have to be delved into with considerable effort in order to reach a conclusion that would have that much impact.

BY MR. SLATER:

Q. If the conclusion that I postulated were the facts, you would agree that that would be about as bad as it gets, right?

MR. FOX: Objection to the

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form. Calls for -- it's argumentative.

A. Once again, if after a complete investigation considered all the facts, if it was established and proven based on objective evidence that information existed that was known was deliberately covered up or anything was falsified, then that would be a very serious violation, yes.

BY MR. SLATER:

Q. Looking now at the Summary, you talked about the fact that there is a "growing consensus about the most critical quality management concepts." And you say, "First among those is that executive management teams are the key to a company's ability to successfully meet quality standards on a consistent basis. Doing so is critical to proper clinical performance of the products of this industry and therefore, ultimately, to global public health."

And you would apply those -- that point to ZHP? Those points would apply to ZHP, right?

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A. I'm sorry, Adam, can you just have that repeated? It got garbled.

Q. This would apply to ZHP, correct?

MR. FOX: I'll object to the form because I didn't hear it.

BY MR. SLATER:

Q. I read the -- I'll do it again.

You say in the Summary that certain -- rephrase.

You say in the Summary that there's a "growing consensus about the most critical quality management concepts. First among those is that executive management teams are the key to a company's ability to successfully meet quality standards on a consistent basis. Doing so is critical to proper clinical performance of the products of this industry and therefore, ultimately, to global public health."

And you would agree that within ZHP, the ultimate responsibility lies with the executive management team, correct?

MR. FOX: Objection to form.

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A. Yes, I would agree it applies to ZHP and everybody else in the industry.

BY MR. SLATER:

Q. Let's go to the last page, please. It's there already, sorry.

The last paragraph of this article says, "Prudent management teams recognize this and support their quality units both philosophically and materially, with strong policies backed up by consistent actions, authority and resources. Failure to do so may have both serious business consequences for the company and potentially even personal consequences for individual executives."

Again, that's a statement that you believe would hold true for ZHP and any company in this industry, right?

A. Yes, any company in this industry.

Q. Going back to the events of 2017, if ZHP knew that there was NDMA in its valsartan as of at least July 2017, yet continued to manufacture that valsartan with

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the zinc chloride process, didn't change anything, didn't tell anybody, every pill manufactured with that process would be adulterated, right?

MR. FOX: Objection to form.

A. I'm sorry, I'm giving some thought to the way you phrased that, not the concept, but just the phraseology.

If there was proven evidence that the process was contributing NDMA at harmful levels, and they allowed that to continue and continued to sell the product, and particularly if there was any deliberate effort to conceal that, then yes, that would be very serious.

MR. SLATER: If you guys need a break, this would be a good point because I'm going to shift to something else. But if you don't need a break, I can do it.

MR. FOX: Let's take a break, Adam, because I have to take care of something else for a few minutes, too.

A. I need a couple minutes.

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How much time do you want to take here?
MR. FOX: About 3:15?
THE WITNESS: Okay. What time is it now?
MR. SLATER: That's fine.
THE WITNESS: Okay. 3:15 is good.
MR. SLATER: Thank you.
THE VIDEOGRAPHER: The time is 2:54 p.m. We are off the record.
(Whereupon, a recess was taken.)
THE VIDEOGRAPHER: The time is 3:23 p.m. We are back on the record.
BY MR. SLATER:
Q. Mr. Chesney, have you seen any indication in anything you've seen that ZHP has ever notified the FDA about the contents of the July 2017 e-mail we discussed earlier?
MR. FOX: Objection to form.
A. The existence of the e-mail itself?
///

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BY MR. SLATER:
Q. Well, the contents we've been talking about, including that there was NDMA in valsartan --
A. Well, the --
Q. -- how it was being created at the quenching of the sodium azide, the sodium nitrite, and that it was a common problem with sartan APIs?
MR. FOX: Objection to form. Argumentative, lacks foundation.
A. There was extensive back and forth with the FDA. ZHP submitted a tremendous amount of scientific data. FDA asked questions, ZHP responded. I've seen a lot of that. Some of it may have contained information that was foundational to that July of '17 e-mail or may not.
But the existence of the e-mail itself, I haven't seen reference. It's just the information that it refers to may have been wrapped up and included in some other discussions that were held with the FDA.
///

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BY MR. SLATER:
Q. I understand you're saying maybe it was, but nothing you can recall seeing as you sit here now, right?
A. No, and nothing specific about that particular e-mail.
Q. Did you see any indication in anything you reviewed where ZHP suggested to the FDA or anybody else that it was known internally that there was NDMA in valsartan, and that this was caused by the quenching of the sodium azide with the sodium nitrite, that that was known before June of 2018? Have you seen anything indicating they ever told that to anybody?
MR. FOX: Objection to form. Lacks foundation, argumentative.
A. Again, I would have to look at the correspondence back and forth to refresh my memory as to what happened when and what they told the FDA about the timeline. But as I sit here, I can't recall anything.
BY MR. SLATER:
Q. I'm going to jump through a

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couple of things with you.
One of the things I noticed in your report was that you said that the time period that you focused on was August 2013 to October 2019, other than, I think, one complaint from 2010 that you found on the FDA website.
Do I understand that correctly?
A. Not exactly. That wasn't a complaint on the FDA website. It was a record of a prior inspection. And there was -- you know, that was not within that bracketed time period.
But the majority of the documents I reviewed were within that bracketed time period.
Q. Do you have any understanding -- rephrase.
Why would the time period you were looking at beginning 2013 when the manufacturing process change was vetted and evaluated in 2011?
A. Well, the primary remit I was given was to opine on what the record showed

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for ZHP's GMP compliance status, and most of the records that I was supplied, the vast majority of them, began in 2013 and ran up until that latter date.

I was able to extract from the FDA website a couple earlier references, and at least one later one when the warning letter was closed out formally by the agency. But most of it was in that time period.

[redacted]

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[redacted]

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[redacted]

BY MR. SLATER:

Q. You talked a lot about the

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events after the 483s, the warning letter, and the establishment inspection report. You talked a lot about what happened after that, and talked about the fact that, well, eventually they got a closeout letter, and eventually they got the import alert over three years later. You talked about that in your report, right?

A. Yes.

Q. The point is that there were violations the FDA found, and then those violations had to be remedied on a going forward basis. And that's what you're talking about would happen on a going forward basis; you're not saying that these violations didn't exist before, right?

MR. FOX: Objection to the form. Assumes facts not established.

A. One of the contributing factors I'm sure in that three-year delay you alluded to was the COVID pandemic. FDA's action in closing out the warning letter probably could have been done much more promptly had it not been for that. That slowed down a lot of

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things at the FDA. In fact, they're still dealing with the backlog caused by that, so that may have been one contributing factor.

You know, that whole process of bringing the warning letter to the fore, issuing that, taking the import alert action and clearing all those things up, those things happen very slowly in normal times, and with the intervention of the pandemic, I'm sure it slowed it even further.

BY MR. SLATER:

Q. Aside from the timing of how long it took, the fact of the matter is that the FDA found some violations, and then ZHP had to take steps to remedy those situations before it could get a closeout letter and get off the import alert, correct?

A. With respect to the warning letter, the FDA's formal position is that that's an advisory action, not a final agency determination of noncompliance.

And what they characterized those items in the warning letter as internally is observations of regulatory

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significance. They don't term them to be violations because they've not truly been adjudicated at that point in time.

Q. I did some reading, and my understanding is that the warning letter is actually a very serious document because the assumption is it's going to get the attention of the company and get the company to fix the situation so that the FDA doesn't have to escalate to direct legal action in court.

A. That's correct. I didn't say it wasn't a serious event. It is a serious event. It's just that the agency's official position is that it is an advisory notification intended to stimulate, bring about voluntary corrective action, and also to serve as prior notice in the event they do have to escalate, then they can make showing that they gave the company the opportunity to correct things voluntarily.

Q. For the companies, for example, that you consult on -- rephrase.

For the companies you consult with, when they get a warning letter, you

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take that very seriously and you make it clear to those companies to take them very seriously, right?

A. Without question, yes.

Q. I mean, a warning letter is not something that happens every day, and it's a big event in a company's lifecycle that they have to really focus on and deal with very, very seriously, right?

A. A warning letter is not something that happens every day to a company, but it's something that happens every day at the FDA. They're not uncommon events.

Q. I guess really, I think we've talked about through, but I got the sense that maybe there was a suggestion that a warning letter, because it's not a binding legal action, that it somehow has some kind of minimal significance. That's not what you're saying?

A. Oh, no, not at all. I'm sorry if I conveyed that impression. That was not what I intended.

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Q. We're going to digress into something really random right now, which is to clear something up actually.

MR. SLATER: Chris, do you have the Exhibit B addendum to the reliance list? I just realized I never marked it as an exhibit. The addendum we got the other day.

MR. FOX: What is this?

MR. SLATER: I'm sorry, what?

MR. FOX: Okay.

MR. SLATER: I think, Chris, this is Exhibit 12 now, right?

MR. GEDDIS: Yes.

MR. SLATER: Okay. Just for everybody to know, we had talked about what exhibit numbers there were. The exhibits have been getting marked sequentially in the deposition. Even though a lot of them had numbers from prior depositions, we've marked them for purposes of this deposition as well so that we know which ones were actually used here, so they're marked

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specific to this deposition as well.
So this is Exhibit 12.
(Whereupon, Chesney Exhibit Number 12 was marked for identification.)
BY MR. SLATER:
Q. Mr. Chesney, we were provided this the other day, a list of additional references as an addendum to Exhibit B.
Are these materials that you have read?
A. Not in their entirety. At the onset of this engagement I accessed a number of things that were publicly available just to get some context and bring myself a little bit more up to speed on what was going on with the nitrosamine issue.
So these are things that I've pulled from various sources, took a look at, took what I could get from them, more for orientation and contextual purposes and not for specific reliance during the formation of the opinion I submitted in this matter.
Q. Were these materials that you

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had available -- rephrase.
Are these materials that you had at least looked at before you signed your report --
A. Yes.
Q. -- or things you looked at after?
A. Yes. I looked at them, most of them, at the very beginning of this engagement back, whatever it was, in June of 2021 when I first started doing the work, just to get a sense of the issues and what some of the guidance documents were that FDA and others have come out with on this topic.
Q. Okay. In terms of the methodology that you followed here -- well, rephrase.
In terms of your normal methodology, if I understood before, normally what you would do when you're evaluating the GMP compliance status for a particular manufacturer would be to evaluate the relevant documents that are available, the internal standard operating procedures that

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would apply, and I think also you said you would do this in a multidisciplinary way where you would rely on subject matter experts with regard to the scientific questions to give input that you could then rely on to give an ultimate opinion.
I don't mean to oversimplify, so if you want to tell me a little more you can, but that was generally my understanding of your methodology for evaluating GMP compliance status.
A. Well, let me expand that thought a little bit, if you may.
If I'm doing this for a client in the sense of either an audit or any other type of consultative activity, then my approach would be more or less the way you mentioned, looking at standard operating procedures perhaps, looking at the actual facility, watching operations, looking at investigations they've done, and things of that sort.
For this engagement what I was provided was a lot of FDA documentation,

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communication from the company and so on.
So the way I approached it was first to try to get myself a little bit of a briefing on the general issues. I had read, as I mentioned before, about the NDMA issues, I thought it would help if I understood a little more depth about what was going on here, so I accessed some of these documents for that purpose. It was just for orientation.
Then when I got into the documents themselves, I looked at them through the same eyes I would have looked at when I was reviewing identical kinds of documents at the FDA, which I did for many, many years. And I relied to a large extent on FDA's published methodology for doing the same thing, which appears for the most part in their compliance program guidance manual which gives -- all of those programs in part Roman Numeral V, gives instructions to reviewers for what kinds of observations should be considered significant and what regulatory pathways are appropriate in

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different fact situations.

So I apply the FDA's own published methodology to determine whether the establishment inspection reports were appropriately classified by the agency based on their own criteria.

I also read the establishment inspection reports to determine if the investigators followed the compliance program requirements, collected the correct information, whether their statements are objective or conclusionary, whether they're substantiated with appended evidence. I have a number of factors that I apply that are really the same that I applied when I was reviewing those reports for many years in the FDA.

Q. So ultimately, if I understand correctly, when you were evaluating the GMP compliance status, you were doing it through the prism of the back and forth with the FDA and the FDA documents for the most part?

A. Largely, yes.

Q. And I think that with regard to

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the -- rephrase.

We've talked quite a bit about this, so I'm not going to go back into it in any detail, but with regard to scientific issues, that's an area where you've told us you would defer. And since you don't have that at this point you didn't offer opinions in your report as to whether or not there were GMP violations because you would need that input before you could form that opinion, correct?

A. Yes, that's correct. And furthermore, the law firm I started working with on this matter, we discussed that angle, and I told him what my limitations were. When we entered into my retention in this matter, I told him there were certain scientific issues that were going to come up that I would not be the best expert to address.

And they understood that, said that they had other people that they were working with that could provide that perspective, and not for me to be concerned

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about that, but just to indicate in my report any areas where I was, in fact, deferring to others. And I attempted to do that as I wrote the report. I think you've seen that.

Q. Got it.

A. Some other documents I relied upon that are referenced in part in the report include the FDA regulatory procedures manual, and certain other publicly available guidance documents that the agency has out there.

Q. And at this point we've also talked about some documents and some information you hadn't seen yet. Ultimately if you were to form an opinion, you would want to be able to be assured that you had the relevant documents in doing so, right?

A. Well, yes. But I believed I had sufficient information there to make general conclusions and form an opinion as to what the overall compliance status of the facility was.

Q. The overall compliance status as we talked about from 2013 to 2019,

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correct?

A. That was the major focus, yes, with some excursion back to as early as 2010.

Q. That excursion was to one investigation, or one inspection?

A. Yes, that's right. I think there was also -- well, no, I guess that would be within the time frame that I bracketed.

I think there was another inspection that -- in one of the establishment inspection reports, the FDA person made a statement that the prior inspection was of a certain date, and when I looked at the record, the public record on the FDA data dashboard, there was an inspection that they weren't aware of that they omitted from their text.

So there were a few little gaps like that.

Q. And overall, for you to be able to form an opinion as to whether GMP was met or not, if you were to do your full-blown methodology, you would want to -- you would

need to have the full relevant documents. And as you've seen today, you didn't necessarily have all those, the necessary testimony to be able to understand what would actually happen, you would need all that in order to form such an opinion, correct?

MR. FOX: Object to the form.

A. If there are material omissions, or if there were material omissions in what I was given to review, I was certainly unaware of that at the time.

And, you know, of course, if things like that come to light, I become aware of them, it's something I would want to see.

BY MR. SLATER:

Q. And you would need to see to be able to form an opinion ultimately if it exists, right?

MR. FOX: Objection to form.

A. Yes. But I don't generally speculate that there's something that is not being provided to me. Unless I'm trying to reach a conclusion and don't have adequate

information, I would not presume to ask a question such as, Is there anything you're deliberately withholding from me for any reason, because I wouldn't assume that to be the case.

BY MR. SLATER:

Q. You assumed you were provided all of the relevant documents, correct?

MR. FOX: Objection to form.

A. I did. And that assumption was bolstered to some extent by my comfort that I had quite a bit of information from which to draw an appropriate conclusion.

MR. SLATER: Why don't we go off the record for five minutes. I may be done, I just want to double-check my notes and then we can -- then I can hand it off to Mr. Fox if he has questions too.

THE VIDEOGRAPHER: The time is 3:44 p.m. We are off the record.

(Whereupon, a recess was taken.)

THE VIDEOGRAPHER: The time is

3:47 p.m. We are back on the record.

MR. SLATER: Mr. Chesney, thank you. I don't have any other questions for you, unless counsel questions you, in which case I may follow up on his questioning.

MR. FOX: I have a few questions, Mr. Chesney.

EXAMINATION

BY MR. FOX:

Q. Do you recall that counsel showed you an e-mail from July 27, 2017, ZHP 296?

A. Yes.

Q. And does that e-mail involve scientific information of the type that you're not an expert to decipher?

A. Yes.

MR. SLATER: Objection. You can answer.

BY MR. FOX:

Q. I'm sorry, did you answer?

A. Yes, it does.

Q. Now, according to --

plaintiffs' counsel indicated that there had been testimony taken on that document. Are you aware that there will be additional testimony about that document?

MR. SLATER: Objection. You can answer.

A. No, I wasn't aware of that.

BY MR. FOX:

Q. Have you spoken to the author of that document?

A. No, I have not.

Q. From the substance of the document that was shown to you and that you read, can you determine definitively what was going on in that document?

MR. SLATER: Objection. You can answer.

A. No. As I said when Mr. Slater asked the question earlier, there are some issues there that are being brought to the attention of upper management, and that seemed to me an appropriate thing to do. But I cannot independently judge fully the significance of the issues.

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BY MR. FOX:
Q. Based on your review, did that document indicate that NDMA was in valsartan API?
A. It alludes to that at one point. But there's -- you know, again, I can't determine how reliable that statement is or how well substantiated it is. Those are the kinds of questions the leadership team should be asking, and others. Once they get that notification, they should ask for a more complete briefing.
Q. Is it your normal practice to opine on company documents?
A. I'm sorry, Mr. Fox?
Q. Is it your normal practice to offer opinions on company documents?
A. Yes, some. If a client asks me to and it's within my expertise, yes.
Q. Okay. Was the document dated July 27, 2017 within your expertise?
A. No.
MR. SLATER: Objection.
You can answer.

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BY MR. FOX:
Q. You were asked questions earlier by plaintiffs' counsel about unknown peaks, correct?
A. Yes.
Q. Do you remember that testimony?
A. I remember the topic, yes.
Q. And did that topic come up in connection with an FDA inspection in May 15th to May 19th of 2017 --
MR. SLATER: Objection.
BY MR. FOX:
Q. -- at the Chuannan plant?
MR. SLATER: Objection. Lack of foundation.
A. I would have to either look at the inspection report or my report to see if there's any mention of that. My recollection is not precise on that.
BY MR. FOX:
Q. Okay. I'm going to ask you to turn to page 35 of your report.
A. Okay. Got it.
MR. SLATER: I'm sorry, what

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page did you say in the report?
MR. FOX: 35.
MR. SLATER: Give me one second. Okay.
BY MR. FOX:
Q. Do you see at the bottom of the paragraph it discusses an analysis of peaks?
A. Sorry, the bottom of the third paragraph, or...
Q. The bottom -- at the bottom of the page, the last six lines of the page.
A. Bottom of the page.
Yes, uh-huh, I have that.
Q. So is the issue of peaks a part of that inspection?
A. Apparently was, yes.
Q. And did ZHP respond to the issue raised with regard to the peaks?
A. Yes, they did.
Q. How did they respond to it?
A. Well, in at least one instance they said -- they characterized it as a, quote-unquote, "ghost peak with no product quality impact."

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Q. Do you understand why they referred to it as a ghost peak?
A. I have a general understanding. Again, I'm not an analytical chemist, I don't do these tests myself, but I have heard that reference made many, many times by pharmaceutical analysts, including those that were in my line of command at the FDA. So I have a general understanding of what it means.
Q. And you reported -- you stated in here that there was a report that in the entire year of 2016, there were nine occurrences out of nearly 95,000 batches.
Do you see that?
A. Yes.
Q. In looking at peaks, is the first step to analyze whether they're real or not?
A. Yes, usually it is.
Q. And is it a possibility that there could be aberrations in the test results?
MR. SLATER: Objection.

You can answer.
A. It certainly is. That can come from a number of different sources, including dirty glassware, contaminated solutions, laboratory error. There a whole host of possible ways that these kinds of ghost peaks can appear, and that needs to be investigated and resolved as one of the possible sources.
BY MR. FOX:
Q. Did the FDA accept that nine occurrences out of nearly 95,000 batches was an aberration?
MR. SLATER: Objection.
You can answer.
A. I don't know what the FDA's opinion about that was.
BY MR. FOX:
Q. Well, does your report indicate that the FDA's action was consistent with the view that the agency accepted the scientific rationale offered by ZHP?
MR. SLATER: Objection.
You can answer.
A. Let me look and see what --

just let me back up for a moment here, Mr. Fox.
Yes, this -- the classification of this inspection reflects that the FDA would have deemed the compliance status of the facility minimally acceptable. That's their official term for that. That generally means there are a few observations, they are minor and not of regulatory significance.
So yes, that's a fair conclusion that they concurred that this did not indicate anything serious.
BY MR. FOX:
Q. And did it indicate, in your opinion, that the facility at that time was operating in compliance with GMP?
MR. SLATER: Objection.
You can answer.
A. Well, I base my opinion on more than just this, but certainly this didn't cause me to hold an opinion that they were not in compliance with GMP.
BY MR. FOX:
Q. I believe your testimony is

that you don't have the scientific background to make an independent judgment with regard to the scientific chemistry issues raised, but you're capable of understanding what the FDA's perception of that scientific evidence was?
A. Yes. My capabilities are sufficient that if a subject matter expert offers me a technical explanation, I can usually follow most of it.
And if I have questions of areas that I don't understand, then I ask further followup questions. Usually we can reach accord to where they can explain it adequately to my satisfaction, and I can understand what they're telling me.
So in other words, I have a modicum of understanding of these things, but I am not an independent subject matter expert.
Q. The fact that a company experiences ghost peaks that are viewed to be an aberration, can a company still be compliant with GMP?

MR. SLATER: Objection.
You can answer.
A. Yes, they can. In fact, in my personal experience, this happens frequently in pharmaceutical testing laboratories.
And my last job in the FDA when I was district director for San Francisco, I had a staff of approximately 50 analysts, of whom 10 or 15 were pharmaceutical chemists. And I know that even in the lab that was in my line of command and control, this issue was not infrequent.
So the FDA itself runs into ghost peaks, they resolve them ad hoc as they come up.
BY MR. FOX:
Q. And during your -- counsel's questioning of you, he showed you a couple sentences here and there in a couple of scientific publications, correct?
A. Yes.
MR. SLATER: Objection.
You can answer.
///

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BY MR. FOX:
Q. Is it outside of your scientific expertise, or lack thereof, to be able to make judgments concerning what was known in the scientific literature and the quality of that knowledge, given the sentences that plaintiffs' counsel showed you today?
MR. SLATER: Objection for multiple reasons, including it's argumentative.
You can answer.
A. I can't evaluate the technical sufficiency of those articles. There are some portions of it that I frankly don't even independently understand, although I might understand a good deal of it.
BY MR. FOX:
Q. Given the fact that you told counsel who retained you of your limited expertise when it comes to scientific issues, does it surprise you that you would not be provided all of the scientific data that may be involved in this case?

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MR. SLATER: Objection.
You can answer.
A. No, it doesn't surprise me, because one of the things -- this was one of the concerns I expressed is, Please don't expect me to be able to opine on the scientific questions. When they come up, I will have to say that I need to defer to people with appropriate expertise, and I was informed that those people would be retained separately and would take those issues up as they arose.
BY MR. FOX:
Q. In connection with the e-mail of July 27, 2017 that were shown you, ZHP 296, would you defer to other people for the correct interpretation of that document?
A. Yes, I would.
MR. SLATER: Objection.
You can answer.
A. Yes, I would.
BY MR. FOX:
Q. Earlier in the day plaintiffs' counsel asked you about the 2011 risk assessment.
A. Yes.
Q. And that was conducted in connection with the change in the manufacturing process?
A. Yes.
Q. Am I correct that you testified that you assumed that nitrosamines was a part of that risk assessment in 2011?
A. I don't think I understood the question if I said that. I was -- what I had in mind was the risk assessment that was done in four stages in 2018 and reported out in the response to the warning letter. That's really what I thought we were talking about, and I may have become a little confused as to the timing.
Q. Okay. So you never -- you never made the assumption that nitrosamines was part of 2011 risk assessment, did you?
MR. SLATER: Objection.
You can answer.
A. No, I did not.
///

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BY MR. FOX:
Q. Is there any reason why you would not make that assumption with regard to the 2011 risk assessment?
MR. SLATER: Objection.
You can answer.
A. The totality of the information that I had before me suggested that the industry at large was not really aware of this problem, nor had they developed robust tests to look for it until much later than that.
This appeared in the two public communications on that topic from the FDA; one I believe in the latter part of 2018, and one in January, I think it was, of 2019 where they repeatedly stated that there was not an awareness of this problem in the industry nor by regulators on a worldwide basis.
So based upon that, I would not have assumed that there was knowledge at ZHP or anywhere else in 2011.
Q. So you're aware of statements by the FDA that indicated that it was not

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part of GMP to look for nitrosamines in this process in 2018?
MR. SLATER: Objection.
A. Yes, I'm aware of those statements. And in those statements, the FDA said it really wasn't feasible for them to even look for that or evaluate it during inspections because there wouldn't be any records that they would be able to review that would reflect that type of analysis had taken place.
BY MR. FOX:
Q. Are you aware of the FDA ever stating that they were still not sure of the root cause of the NDMA impurity in the valsartan API?
MR. SLATER: Objection.
You can answer.
A. There's a statement that's still being worked on, I believe, in the 2019 pronouncement. The specifics escape me. I'm not looking at it right at the moment. But they did make a statement to that effect. I believe it was 2019 January statement.

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MR. FOX: Why don't we put up the -- why don't I put up a document here. Can we go off the record for a second until I get the technology down?
THE VIDEOGRAPHER: The time is 4:02 p.m. We are off the record.
(Off the record.)
THE VIDEOGRAPHER: The time is 4:04 p.m. We are back on the record.
(Whereupon, Chesney Exhibit Number Defendant 1, was marked for identification.)
BY MR. FOX:
Q. Mr. Chesney, I'm showing you a document of an FDA public statement made on January 25, 2019.
Do you see that?
A. Yes.
Q. And this is reference 91 in your report?
A. I'm not looking at the reference numbering list, but give me a moment, I will.

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Yes, that's it.
Q. And if I bring you down to the last paragraph of this page, and I'll just read it to you, it says, "Today, we want to provide an update on this ongoing investigation and outline the steps we've taken to identify the root causes of the nitrosamine impurities and to prevent a recurrence of this episode in the future."
Do you see that sentence?
A. I'm sorry, no, I don't. What I'm looking at starts "last summer."
Oh, there. Okay. "Today, we want to provide an update." Now I see it, yes.
Q. And so this was an update of an earlier statement that the FDA made in August of 2018?
A. Yes.
Q. And does this indicate to you that they're still identifying -- trying to identify the root causes of the nitrosamine impurities of valsartan?
MR. SLATER: Objection.

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A. Yes, it says it "continues to be an exhaustive effort led my a multidisciplinary team," which is the point I've been trying to make here today, that that's typically the way things are done at FDA. So I'm not surprised by that. A number of people in collaboration with global regulators.
And they go on to say, "While we're still investigating the root causes of the impurities, our ongoing effort has determined that the impurities may be generated when specific chemicals and reaction conditions are present."
So they're saying the investigation is ongoing, they have what sounds like a hypothesis in their sights, but it appears to be not yet concluded.
BY MR. FOX:
Q. If we go to the next page, do you see where it says in the beginning of the page, "To implement a risk assessment for any genotoxic impurity"?
A. I haven't found it yet. Sorry.

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Oh, there, "To implement a risk assessment." All right. I've got it.

Q. And doesn't that last sentence of the paragraph indicate that the FDA had now just uncovered the risk of nitrosamine impurities in the manufacturing steps involved in ARBs?

MR. SLATER: Objection.

You can answer.

A. I'm sorry, I was still reading the sentence, Mr. Fox. Could you repeat the question for me?

BY MR. FOX:

Q. Doesn't the FDA state in January 2019, quote, "Now that we've uncovered the risk of nitrosamine impurities in the manufacturing steps involved in ARBs, we'll incorporate the findings into ongoing policy development"?

A. Yes, they say exactly that.

Q. It says here -- do you see the sentence where it says, "Tests are selected based on assessments of what impurities may develop as a result of the manufacturing

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process. In other words, it generally needs to be recognized that there's a risk of an impurity occurring as a result of a manufacturing process to know the impurity should be tested for."

Do you see that?

A. Yes, I do.

Q. Can you read the next sentence into the record, "Our investigation"?

A. "Our investigation into ZHP's process identified that a change made to the manufacturing process likely led to this impurity, and that the impurity went undetected by global regulators, including the FDA, for a period of time."

Q. Can you read the next sentence?

A. Yes. Do you want me to read the whole paragraph?

Q. Sure, that would be fine.

A. "Before we undertook this analysis, neither regulators nor industry fully understood how NDMA or NDEA could form during this particular manufacturing process. This is troubling to us and we know it's

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troubling to the public. This concern is appropriate. Among other steps, we need to take actions that would prevent a similar situation from occurring. We are making important strides at understanding how these impurities occurred, mitigating the risk to patients and learning what steps need to be taken to prevent this from occurring again in the future."

Q. Does this indicate -- have implications for when GMP would have been implicated in connection with nitrosamines?

MR. SLATER: Objection.

You can answer.

A. I'm sorry? Was someone going to interject there?

MR. SLATER: I just objected to the form. You can answer.

THE WITNESS: Okay.

Yes, it indicates to me that certainly prior -- or as of the time of this transmittal to the public, there was enough understanding that companies should be pretty well aware.

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Prior to that time, the statement seems to say that there was not general recognition that this was a risk, and that, therefore, GMP would not require testing for something that no one had awareness could constitute a risk.

BY MR. FOX:

Q. If we go to the next page, can you read the first line of the paragraph beginning "During this time"?

A. Sure. "During this time, our scientists have developed and refined novel and sophisticated testing methods specifically designed to detect and quantify the NDMA and NDEA in all ARB medicines."

Q. And this is something that occurred between 2018 and 2019?

A. Yes, because this was not the case in the earlier 2018 public statement, but here we have it showing us January 25, 2019.

(Whereupon, Chesney Exhibit Number Defendant 2 was marked for

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identification.)
BY MR. FOX:
Q. I'm showing you now the earlier statement of the FDA that was referred to. Can you see that? Do I need to lower it?
A. You're going to need to shrink it a little bit, because the panel with all our pictures is overlapping.
There, now I've got it. That's fine right there.
Q. This is the FDA statement of August 30, 2018.
Do you see that?
A. Yes.
Q. And this describes the FDA's actions after learning about the impurity in the valsartan, correct?
A. Yes.
Q. If we go to the second page of it, maybe the third page, do you see the paragraph that says, "Based on information"?
A. Yes.
Q. Can you read that into the record, please?

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A. The whole paragraph?
Q. Yes, please.
A. Sure. "Based on information provided regarding ZHP's manufacturing processes, we believed (but did not have proof) that the impurity resulted from changes that ZHP made to the manufacturing process for its API. We needed to identify the root cause of the problem and evaluate ZHP's explanation. After assessing information about ZHP's manufacturing processes and the changes ZHP made over time, we identified how its processes could have led to the presence of NDMA in their API."
Q. Can you continue with the next paragraph?
A. "Specifically, a combination of conditions, which include certain chemicals, processing conditions and production steps, could lead to formation of the NDMA impurity. We believe that these risks are introduced through a specific sequence of steps in the manufacturing process, where certain chemical reactions are needed to form the active

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ingredient. Before we undertook this analysis, neither regulators nor industry fully understood how NDMA could form during this process."
Q. Let me just stop you there for a second.
A. Okay.
Q. Is that an important fact in connection with judging cGMP with regard to nitrosamines?
MR. SLATER: Objection.
You can answer.
A. Yes, it is, because it speaks to the feasibility of doing this and the general awareness in the industry of it.
BY MR. FOX:
Q. Given this extensive -- you would say the FDA's investigation was extensive, correct?
MR. SLATER: Objection.
You can answer.
A. I've only reviewed the records on ZHP, but their track record is pretty extensive there. I'm not sure what they did

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with the other manufacturers.
BY MR. FOX:
Q. Okay. But certainly this public statement is reflecting an extensive investigation that the FDA undertook of this matter?
A. Yes, it --
MR. SLATER: Objection. Form.
A. It infers that. It doesn't describe the full scope of the investigation with specifics, but it's implicit, yes.
BY MR. FOX:
Q. Now, if you continue with the paragraph that says "We are still."
A. "We are still not 100 percent sure that this is the root cause of the problem. Full understanding will require correlation of multiple test results from valsartan APIs made by different processes with the various process steps used by different manufacturers or at different times. We need to determine how NDMA can be formed and why it is not separated from the API during purification."

Q. Those statements by the FDA, is that important information for you in rendering an opinion with regard to compliance with cGMP by ZHP?
A. Yes, it is.
Q. Can you read the next paragraph, please?
A. "Once we understand the way or ways that the NDMA impurity can occur as a by-product of the manufacturing process, we will make sure" that these -- "make sure these conditions are evaluated in API synthetic processes so that, in the future, testing for this impurity would be required if there was a risk of NDMA formation."
Q. And again, is that an important factor in rendering an opinion with regard to ZHP's compliance with cGMP with regard to nitrosamines?
MR. SLATER: Objection.
You can answer.
A. Yes, because it lays out a two-pronged test to determine if something -- if this is GMP or not. One is, is there a

risk of NDMA formation; and two, if so, what is does the testing show.
BY MR. FOX:
Q. Okay. If you go down a little bit further, do you see the sentence that begins "We employ"?
A. Yes.
Q. Can you read that into the record, please?
A. "We employ robust teams of organic chemists, as part of our newly established Office of Pharmaceutical Quality, to review applications and referenced information to look for steps - and manufacturing changes - where these risks could be introduced."
Q. And if you look at the last sentence on the page, can you read that into the record?
A. "In other words, it needs to be recognized that the risk of an impurity can occur in order to know that it should be tested for."
Q. Is it fair to say that prior to

this date, the FDA did not understand there to be a risk of an impurity in this manufacturing process?
MR. SLATER: Objection.
You can answer.
A. It is. That's what the agency states in this public statement.
BY MR. FOX:
Q. Let's see. I lost my place.
Okay. If we go to the next page here, do you see -- can you read into the record the sentence beginning with the word "Because" in this top paragraph?
A. Yes. Do you want me to read that?
Q. Please.
A. Okay. "Because it was not anticipated that NDMA would occur at these levels in the manufacturing of the valsartan API, manufacturers would not have been testing for it. They would not have records that help identify this issue during an inspection. So this particular risk would not have been identified on an inspection.

As we develop a better understanding of the root cause of NDMA formation, and develop a way to detect NDMA in valsartan or other ARBs, we can ensure that appropriate testing is performed in the future."
Q. Again, is this an important fact in determining whether or not GMP was compliant in connection with nitrosamines in 2018?
A. Yes.
MR. SLATER: Objection.
You can answer.
A. Yes.
BY MR. FOX:
Q. And before 2018, correct?
A. Yes.
Q. And is it true that the FDA is again stating that they're still seeking to better understand the root cause of the formation of this impurity? Is that right?
MR. SLATER: Objection.
You can answer.
A. Yes.
///

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BY MR. FOX:
Q. And it's also saying in August of 2018 that they need to find better ways to detect it.
MR. SLATER: Objection.
You can answer.
A. Yes.
BY MR. FOX:
Q. Is it your testimony that the compliance record of ZHP was in accord with or even better than much of the industry during the period that you reviewed?
MR. SLATER: Objection.
You can answer.
A. Yes. But they had many inspections that led to no observations at all, and most others, while they might have had a small number of observations, they were classified by the agency as voluntary action indicated, which is a mid-level classification that does not reflect a serious state of noncompliance.
BY MR. FOX:
Q. Did the FDA ever determine that

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the nitrosamine or NDMA present in the valsartan was the result of a violation of GMP?
MR. SLATER: Objection.
You can answer.
A. I don't -- I've never seen them make that specific correlation. In the warning letter they raised certain concerns, but I don't believe they ever came right out and made that connection.
BY MR. FOX:
Q. So as far as you understand, the FDA never made a determination that the impurity existed in the valsartan as a result of a failure to comply with GMP?
MR. SLATER: Objection.
You can answer.
A. I never saw anything that connected those two issues directly.
BY MR. FOX:
Q. Are you aware of any GMP violation that would render all of the products of ZHP adulterated?
MR. SLATER: Objection.

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You can answer.
A. Well, hypothetically I suppose you could use your imagination and come up with something that would be so global in scope that it would cause that.
But usually when that is the case, and all the products at a given facility come under that kind of cloud, it's not just because of any one GMP deviation, it's because there are multiple ones of a systemic and repeated nature across all of what FDA calls product classes in that particular -- profile classes, pardon me, in that particular facility.
BY MR. FOX:
Q. And you have not seen that in connection with ZHP here, have you?
A. No.
MR. SLATER: Objection.
You can answer.
A. No, I haven't.
BY MR. FOX:
Q. And did the FDA ever make a final determination of a GMP violation by

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ZHP?
MR. SLATER: Objection.
You can answer.
A. I believe the import alert that they were placed on, along with many, many, many other companies, was primarily predicated upon GMP issues. But again, there was no specific linkage to the occurrence of NDMA.
BY MR. FOX:
Q. So was the alert due to the potential of an impurity being in the drug?
MR. SLATER: Objection.
You can answer.
A. The alert is very nonspecific. It gives a general statement with respect to GMP compliance, I believe it's one sentence, and then there's a list of dozens and dozens and dozens of companies that follow that are on the import alert for that reason. So it's very hard to tell anything specific from the import alert.
BY MR. FOX:
Q. And the language that you're

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referring to, that's template language at the top of the document?
A. It is.
MR. SLATER: Objection.
You can answer.
A. It is.
And I might add that the standard that FDA applies by statute to bring an import alert action is one of an appearance of a violation, not even a preponderance of the evidence, let alone beyond a reasonable doubt. The standard is very, very low.
And I'm getting that directly out of the Food, Drug and Cosmetic Act Section 801. If it appears to be in violation, that's sufficient to take an import alert action. It's a very low standard.
BY MR. FOX:
Q. Did the FDA ever make a finding that the NDMA contamination was due to a cGMP violation?
A. I've never seen them connect --

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MR. SLATER: Objection.
You can answer.
A. I've never seen them connect those two issues directly in anything they've said in writing.
BY MR. FOX:
Q. With regard to ZHP?
A. With regard to ZHP.
MR. FOX: I think that's it for me, Adam.
MR. SLATER: I'm going to continue now, Mr. Chesney.
FURTHER EXAMINATION
BY MR. SLATER:
Q. Did you read the deviation investigation reports that ZHP created and submitted to the FDA?
A. You know, I read an awful lot of information. And to answer your question whether I did or did not look at those, I would have to go back and look at them again just to be sure. But I believe that I did.
Q. I didn't see any discussion of them in your report.

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A. I read a lot of their investigation information, particularly what was in the response to the 483 of the 2018 inspection which raised most of these issues, and also the warning letter that followed. There was a tremendous amount of highly detailed information. One of those transmittals alone was 230 pages.
So to the extent that constituted in whole or in part the deviation investigations, I can't say from memory. It was very extensive.
Q. All right. Well, I didn't ask you about all that stuff.
I asked you if you saw the deviation investigation reports, and did you talk about them in your report. I don't see any discussion of them at all in your report. Is there something in the report I've overlooked?
A. Well, I doubt that there's anything in the report you've overlooked.
What I'm saying is what constituted a deviation investigation report

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may well have been the information in the warning letter response and other documents that I reviewed. They also included a number of attachments.
Q. Are you just speculating as you go right now?
A. No. I'm trying to say that I can't answer your question with definity because I don't know what you mean when you say "a deviation investigation," and I'm not sure whether it was included or not included in any of the materials that I did review.
MR. SLATER: Okay. Chris, let's go to exhibit -- let's take down whatever this is, if you could, Tom.
MR. FOX: Sorry.
MR. SLATER: That's okay.
Chris, this might take a second, but could you put up Exhibit 204, please, the deviation investigation report prepared July 20, 2018? That's 20 -- oh, you know what, you have the -- that's what I want.
///

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BY MR. SLATER:
Q. Does this document look familiar to you? It's Exhibit 204 from a prior deposition.
A. I don't recognize it immediately.
Q. All right. Because you were saying something about some generic deviation investigation report, and you said you didn't know what it was. I'm showing you, that's the actual title of a document.
A. I understand that.
Q. It's very simple. Hang on.
A. No, it's not that simple. I reviewed other documents that contained attachments such as standard management procedures and things like that.
And when you asked me the question before, I didn't know whether this was one that might have been included in one of those other packages, or I may have seen it but just not as a standalone document.
Q. I saw no discussion of this document at all in your report. Is there

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something in there that I may have overlooked, or am I correct that you didn't discuss this document at all?
A. Not as a standalone document, no. And the data --
Q. That's all I asked you, though, so I don't need an explanation beyond that, okay?
A. Okay.
MR. SLATER: Let's go to ZHP, the last four digits are 4386, Chris. It's 22 of 33.
A. Is this the same report, or is this something different?
Q. It's the same report.
MR. SLATER: Can you blow up the bottom part, Chris, under Section 3.8 with that heading? Perfect.

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[redacted]
BY MR. SLATER:
Q. Now, you were asked some questions about ghost peaks. Do you know what a ghost peak is? Do you know how that's defined?
A. I know that they occur frequently. And as I said before, this is not something I do for a living. I've just heard the term used very often to describe unidentified peaks, they're usually not very large in terms of quantity that may arise from any of a number of different factors and require some investigation to resolve.
Q. Do you know the difference between a ghost peak and an aberrant peak?
A. No.
Q. Do you know if all unknown peaks are ghost peaks?
A. No, I think when -- you call something a ghost peak when it's not possible to define with specificity what's causing it, and there are a number of different possible contributing factors that requires an

investigation to try to iron that out.
Q. You're guessing at the definition when you just said that, right? You don't know if you're right?
A. I'm telling you what my understanding is. If my understanding is incorrect, then so be it. But that term has been used to me for a number of years, and the context has usually been that.
Q. I'm not going to go through those FDA statements that counsel had you read, but I want to ask you a question.
There was a point where the FDA was explaining why they didn't find the problem with the NDMA in the valsartan on their inspections.
Do you remember you were reading that part?
A. Yes.
Q. You understand we're not suing the FDA here; we're suing ZHP, right?
A. Of course.
Q. Okay. And if -- rephrase. And if the manufacturer -- rephrase.

You said in your report that the FDA primarily relies upon drug manufacturers to voluntarily follow the law, right?
A. Yes.
Q. That's how the system works, is the companies are supposed to follow the regulations and follow their SOPs so that things like this don't happen, right?
MR. FOX: Object to the form. Argumentative.
A. Yes.
MR. SLATER: Chris, let's go, if we could, to the Warning Letter, ZHP 213, the November 29, 2018 Warning Letter. Thank you.
(Whereupon, Chesney Exhibit Number 13 was marked for identification.)
BY MR. SLATER:
Q. You've seen this document, correct?
A. I have.
Q. And right there on the first

page in the second sentence it says, "This warning letter summarizes significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API)," right?
A. Yes.
Q. And then the next paragraph says, "Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your API are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act, 21 USC 351(a)(2)(B)," right?
A. Yes.
Q. And then the FDA says that they reviewed the August 26, 2018 response from ZHP to the 483s, and acknowledged receipt of your subsequent correspondence, right?
A. That's right.
Q. Let's go through number 1 a little bit. "Failure of your quality unit to ensure that quality-related complaints are investigated and resolved." It says,

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"Valsartan API."

You've read this paragraph, right?

A. I have. And I've also read ZHP's response to all this to get some balance to the situation.

Q. Did I ask you about ZHP's response?

A. No, you didn't.

Q. Okay. By the way, to the extent that ZHP withheld information from the FDA as part of its investigation, that would be unlawful, correct, if that information was material to the investigation?

MR. FOX: Objection to the form. Calls for a legal conclusion.

A. That's not an area that I get myself into as a rule. Whether there's been a material misrepresentation or not is -- that's usually a legal conclusion.

BY MR. SLATER:

Q. Okay. This says under number 1, "Your firm received a complaint from a customer on June 6, 2018, after an unknown

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peak was detected during residual solvents testing for valsartan API manufactured at your facility. The unknown peak was identified as the probable human carcinogen N-nitrosodimethylamine (NDMA). Your investigation (DCE-18001)" -- and I'll tell you for the record that's the deviation investigation report I just showed you. If you need me to show it to you again I'll show you and show you the number matches up.

A. No, that's all right. I take your word for it.

Q. -- "determined that the presence of NDMA was caused by the convergence of three process-related factors, one factor being the use of the solvent dimethylformamide (DMF). Your investigation concluded that only one valsartan manufacturing process (referred to as the zinc chloride process in your investigation) was impacted by the presence of NDMA.

"However, FDA analyses of samples of your API, and finished drug product manufactured with your API,

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identified NDMA in multiple batches manufactured with a different process, namely the trimethylamine process, which did not use the solvent DMF. These data demonstrate that your investigation was inadequate and failed to resolve the control and presence of NDMA in valsartan API distributed to customers."

Do you see what I just read?

A. Yes.

Q. You've told me you didn't evaluate the TEA process, the triethylamine process, and you didn't talk about it in your report at all, right?

A. That's correct.

[redacted]

not something you addressed at all in your report, right?

A. That was something that falls in the area of process chemistry, and I again would defer to people with the appropriate

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expertise to evaluate that.

[redacted]

MR. FOX: Objection to form.

BY MR. SLATER:

Q. Wondering if you know that.

A. No, I haven't seen that information.

Q. Going back to the document now, the warning letter, it says, "Your investigation also failed:", the first bullet point, "To include other factors that may have contributed to the presence of NDMA."

Second bullet point, "To assess factors that could put your API at risk for NDMA cross-contamination.

And then the third bullet point, "To evaluate the potential for other mutagenic impurities to form in your products."

Do you see that?

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A. Yes, I do.
Q. Then the next paragraph, "Our investigation also noted other examples of your firm's inadequate investigation of unknown peaks observed in chromatograms."
Do you see that?
A. Yes.
Q. If you go to the next paragraph, it says, "Your response states that NDMA was difficult to detect. However, if you had investigated further, you may have found indicators in your residual solvent chromatograms alerting you to the presence of NDMA. For example, you told our investigators you were aware of a peak that eluted after the toluene peak in valsartan API residual solvent chromatograms where the presence of NDMA was expected to elute. At the time of testing, you considered this unidentified peak to be noise and investigated no further."
And then it goes through the API validation batches, and they indicate that these "show at least one unidentified

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peak eluting after the toluene peak in the area where the presence of NDMA was suspected to elute."
So I read that as a preview to this question, which is the FDA didn't think -- you would agree with me the FDA didn't think that ZHP did a good job in evaluating unknown peaks, right?
MR. FOX: Objection to form.
A. That's what the warning letter alleges, yes.
BY MR. SLATER:
Q. And then if you go to the next paragraph at the bottom of this page, page 2 of this warning letter, in the middle of it, it says, "FDA has grave concerns about the potential presence of mutagenic impurities in all intermediates and API manufactured at your facility, both because of the data indicating the presence of impurities in API manufactured by multiple processes, and because of the significant inadequacies in your investigation."
So again, there's some what the

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FDA termed grave concerns about what was going on in ZHP's facilities, right?
A. That's correct.
MR. SLATER: Now let's go to the page number 4, please, Chris.
Q. Heading number 2, "Failure to evaluate the potential effect that changes in the manufacturing process may have on the quality of your API."
That's relating to the risk assessment, correct?
A. Yes.
Q. It says, "In November 2011 you approved a valsartan API process change that included the use of the solvent DMF. Your intention was to improve the manufacturing process, increase product yield, and lower production costs. However, you failed to adequately assess the potential formation of mutagenic impurities when you implemented the new process. Specifically, you did not consider the potential for mutagenic or other toxic impurities to form from DMF degradants, including the primary DMF degradant,

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dimethylamine. According to your ongoing investigation, dimethylamine is required for the probable human carcinogen NDMA to form during the valsartan API manufacturing process. NDMA was identified in valsartan API manufactured at your facility."
Do you see what I just read?
A. Yes.
Q. The failure to adequately assess the potential formation of mutagenic impurities when ZHP implemented the new process, that would be a cGMP violation, correct?
MR. FOX: Objection to form.
A. I think you used the word "potential." That's not what it says, but...
BY MR. SLATER:
Q. It says "potential formation." It says, "However, you failed to adequately assess the potential formation of mutagenic impurities when you implemented the new process."
And my question to you is, the failure to adequately assess the potential

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formation of the mutagenic impurities, that's a violation of cGMP, right?
MR. FOX: Objection to form.
BY MR. SLATER:
Q. If that's what happened, it's a violation, correct?
MR. FOX: Objection to form.
A. I'm sorry, I lost you as you were reading. You must have skipped ahead somewhere and I was reading the wrong sentence.
Can you direct me where you're reading?
BY MR. SLATER:
Q. I'm in the first paragraph under number 2, the third line.
A. Oh, okay.
Q. It says, "However, you failed to adequately assess" --
A. Okay. I'm sorry. I skipped ahead to far.
Q. No problem.
You see it says, "However, you failed to adequately assess the potential

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formation of mutagenic impurities when you implemented the new process"?
A. Yes.
Q. That would be a cGMP violation, right?
MR. FOX: Objection to form.
THE WITNESS: I'm sorry, what did you say?
MR. FOX: I objected to the form.
What was the answer?
MR. SLATER: You talked over it, that's why I'm asking him.
BY MR. SLATER:
Q. Is that correct?
A. Yes, that's correct.
Q. Going now to the second paragraph under section -- the heading section 2, "You also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in your valsartan API before you approved the process change."

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Stopping right there, that's a cGMP violation, correct?
MR. FOX: Objection to the form.
A. That should be done, yes.
BY MR. SLATER:
Q. It says further, I'm going to continue to read, "You are responsible for developing and using suitable methods to detect impurities when developing, and making changes to, your manufacturing processes. If new or higher levels of impurities are detected, you should fully evaluate the impurities and take action to ensure the drug is safe for patients."
You agree with that statement, that was an obligation of ZHP, right?
MR. FOX: Objection to the form.
A. I agree that's a correct statement.
BY MR. SLATER:
Q. Go to the next paragraph.
It says, "Your response" -- now

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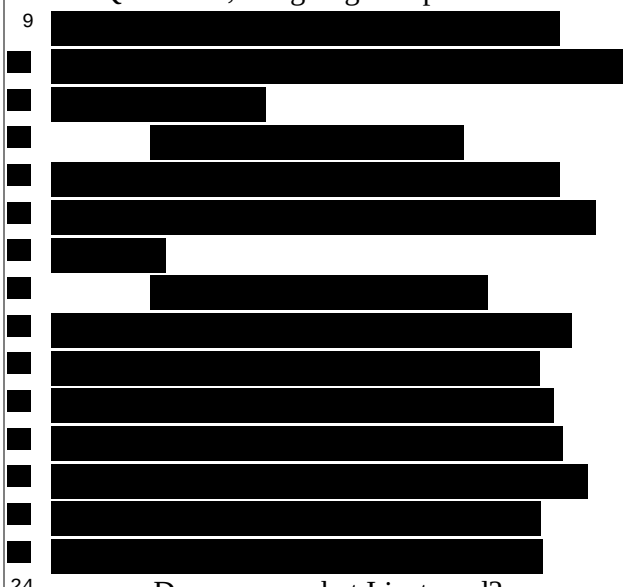
they're talking about that response that you were telling me about before, that you got that long response from ZHP and you read it. Remember you told me that?
A. Wait. There are two responses. The one they're referring to here is a response to the 483.
There's also a response to this warning letter where they take issue with a number of these points, provide additional data, and a considerable level of detail.
So this letter by itself makes certain assertions, but it's not the complete story.
Q. Looking now at the third paragraph, the FDA says, "Your response states that predicting NDMA formation during the valsartan manufacturing process required an extra dimension over current industry practice, and that your process development study was adequate. We disagree."
MR. FOX: Adam, let me object.
Where are you, Adam?
MR. SLATER: Third paragraph

under number 2. I wasn't planning to do any of this, you brought it up, so I'm just going to hammer the nail.
BY MR. SLATER:
Q. Third paragraph under number 2, I'll go back to it again. "Your response" -- rephrase.
The third paragraph under number 2 says, "Your response states that predicting NDMA formation during the valsartan manufacturing process required an extra dimension over current industry practice, and that your process development study was adequate. We disagree."
Do you see that?
A. I do.
Q. So the FDA felt that the process development study was inadequate and there was a violation of cGMP, correct?
MR. FOX: Objection to form.
A. They -- I don't agree with your statement there, and it's inconsistent with their public statements both before and after this warning letter. But that's what they

say.
BY MR. SLATER:
Q. Coming back to my question, the FDA disagreed with ZHP that they couldn't have known about the potential formation of the NDMA, right?
MR. FOX: Objection to form.
A. They disagreed that it required an extra dimension over current industry practice. That's what the reference is to.
BY MR. SLATER:
Q. The next sentence says, "We remind you that common industry practice may not always be consistent with CGMP requirements and that you are responsible for the quality of drugs you produce."
You agree with that statement, right?
A. I do.
Q. So when ZHP decided to develop this zinc chloride process that had not been used before, they were responsible for the quality of the drugs that would be manufactured with that new process, right?

MR. FOX: Objection to form.
A. Yes, they were responsible.
BY MR. SLATER:
Q. And the fact that nobody else had been manufacturing by that process previously doesn't change the fact or excuse the fact that they failed to evaluate fully the risks from that new process?
MR. FOX: Objection to form.
A. The fact that nobody else was using the process does not relieve them of the necessity to evaluate it fully.
MR. SLATER: Okay. Let's take that down. Let's go, Chris, if we could, to Exhibit 212.
(Whereupon, Chesney Exhibit Number 14 was marked for identification.)
BY MR. SLATER:
Q. This was previously marked as Exhibit 212 at a deposition of Peng Dong. I assume you haven't seen this. It's a draft of a deviation investigation report.
A. From the cover page I couldn't

tell you.
And could you make it a little bit larger? It's a little small on my screen.
Q. No problem.
A. The cover page I don't recognize, but I don't know.
Q. Well, I'm going to represent to



Do you see what I just read?

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A. Yes.
Q. And if that's what happened, that was a violation of cGMP, as we've gone through earlier, correct?
MR. FOX: Objection to form.
A. Again, I can't characterize an individual occurrence like that as a violation or not a violation. That requires a lot more consideration.
But it's concerning and certainly worthy of everyone's attention, including those at the company that received this report.
MR. SLATER: Take that down.
The next thing I'd like to go to, if we could, is -- I believe it was Exhibit 430. It's the August 26, 2018 response to the 483 letter.
(Whereupon, Chesney Exhibit Number 15 was marked for identification.)
MR. SLATER: Signed by Jun Du.
MR. GEDDIS: Give me a second.
THE VIDEOGRAPHER: Excuse me,

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Attorney Slater?
MR. SLATER: Yes.
THE VIDEOGRAPHER: May we go off the record for a moment? I have approximately ten minutes left on this backup media recording.
MR. SLATER: No, I want to continue. We'll be done in ten minutes. I'm also through.
THE VIDEOGRAPHER: Okay, sir.
MR. SLATER: Don't worry about it. If I start to run into it and get to two minute, let me know.
THE VIDEOGRAPHER: The Zoom is going, just the backup.
MR. SLATER: Are we okay?
THE VIDEOGRAPHER: The Zoom is recording, yes. The backup media had approximately ten minutes left.
MR. SLATER: Okay. Just let me know if we get to two minutes.
THE VIDEOGRAPHER: Okay, sir.
MR. SLATER: While Chris is looking for that, you might as well --

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okay. He got it.
BY MR. SLATER:
Q. Okay. This is the August 26, 2018 letter from Jun Du of ZHP to the FDA.
You've seen this, correct?
A. Yes, I have.
Q. Let's go to page 3 of 4, please.
MR. SLATER: And let's blow up that middle paragraph, if we could, just so we can all see it. Okay. Perfect.

MR. FOX: Objection to the form.

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A. You showed me a document that had a suggestion of that. But as I indicated, it's got some technical aspects that I'm not comfortable evaluating, and would trigger a lot more questions in my mind before I would be prepared to make a definitive statement about it.
BY MR. SLATER:
Q. The July 2017 e-mail doesn't make any suggestion, it states definitively that there's NDMA in valsartan, the root cause is the quenching of the sodium azide in the presence of sodium nitrite, and says it's a problem with all the sartans, across sartans. That's what it says. It doesn't speculate about it; it makes those factual statements, right?
MR. FOX: Objection. Object to the form. Argumentative.
A. It presents the information in that way, yes.
BY MR. SLATER:
Q. All of which you can tell me sitting right now is accurate because we know

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historically that was all proven true, those factual statements, right?
MR. FOX: Objection to the fact -- objection to the form.
A. Most of that proved to be correct. But again, putting myself in the position of having received that at that point in time, I would have had a host of more questions.
BY MR. SLATER:
Q. It's not some of it has been proven correct, all of those three things have been proven correct, right?
MR. FOX: Objection to the form. Argumentative.
A. I, at this point, am not sure specifically what we're talking about in terms of all of them.
BY MR. SLATER:
Q. There's NDMA in valsartan, it's caused when they quench the sodium azide with sodium nitrite, and it's a problem with multiple sartans. That's been proven true, right?

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MR. FOX: Objection to the form.
A. Yes. At a high level, yes, that's true.
BY MR. SLATER:
Q. And just to be clear, Jun Du represented that this wasn't learned until June of 2018. That's what he represented to the FDA, right?
MR. FOX: Objection to form. Argumentative, document speaks for itself.
MR. SLATER: All right. Look, I'll ask it again.
BY MR. SLATER:
Q. It's a fact that ZHP has always represented to the FDA that those facts weren't learned until June 2018, right?
MR. FOX: Well, ask the question.
BY MR. SLATER:
Q. Can you answer that? That's correct, right?
A. I'm sorry, I heard two people

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talking there. I wasn't sure where we were with this.
Could you restate the question, because I heard multiple people.
Q. Sure.
ZHP has always told the FDA it did not learn of what we just talked about until June of 2018 at the earliest, right?
A. That's when they reached the final conclusion, yes. That's what they told the FDA.
Q. Well, they claimed that they didn't even know there was NDMA in the valsartan until June of 2018, right?
MR. FOX: Objection to form.
A. That they -- they wouldn't have said they knew it until they were sure of it.
MR. SLATER: Let's take that down and go to Exhibit 312, the establishment inspection report.
(Whereupon, Chesney Exhibit Number 16 was marked for identification.)
MR. SLATER: Do we have at

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least another five minutes left on that backup? Okay.
BY MR. SLATER:
Q. Here on the screen we have the Establishment Inspection Report, Exhibit 312.
Do you see that?
A. Yes.
Q. And I just want to go to page 20 of 58. Looking at the paragraph that says, "During the opening presentation."
MR. SLATER: Let's blow that up a little bit. Perfect.
Q. This states, "During the opening presentation on July 23, 2018, Mr. Du explained how the firm came to know Valsartan manufactured by the firm could contain the genotoxic impurity NDMA. Mr. Du stated Novartis placed an order with the firm for 45 Metric Tons of valsartan." And then he goes through it and talks about how it was Novartis that told ZHP of this issue, right?
A. Let me read the paragraph here.
(Witness reviewing document.)
A. Okay. So okay, I've read the

paragraph. Now, what was the question again?
Q. This is reciting what Jun Du told the FDA at the time of the inspection of July 23, 2018, right?
A. Yes.
Q. Based on the content of the e-mail from July of 2017 showing that ZHP already knew there was NDMA in the valsartan and why it was occurring, when Mr. Du spoke to the FDA that day, he lied to the FDA, correct?
MR. FOX: Objection. Calls for conclusion, speculation.
A. I can't conclude that based on what I see here.
BY MR. SLATER:
Q. What Jun Du told the FDA was untrue in comparison to what that July 2017 e-mail shows, correct?
MR. FOX: Objection to form. Beyond his expert report, calls for a legal conclusion.
A. Again, I am still not confident of the state of the firm's awareness,

notwithstanding Dr. Lin's statement in his July 17th e-mail. For me to accept that as fact, I would need to see considerably more backup information that that statement is based upon and have it evaluated by scientific experts to be sure it's right.
Because an allegation such as that that he was not being truthful is very serious and needs to be vetted in considerable detail, and I think FDA would approach it the same way.
BY MR. SLATER:
Q. If ZHP wasn't truthful with the FDA as to when they learned there was NDMA in the valsartan and how it was occurring, if that occurred, that's a very, very serious violation, right?
MR. FOX: Objection. Asked and answered.
A. Yes, that would be a significant violation, yes.
MR. SLATER: I don't have any other questions unless your counsel wants to ask you more.

FURTHER EXAMINATION
BY MR. FOX:
Q. Mr. Chesney, can something that occurred in this instance with impurity found in valsartan, could that have occurred even though everyone followed the law?
MR. SLATER: Objection.
A. Yes.
BY MR. FOX:
Q. In regard to GMP and cGMP, what does the "C" stand for?
A. Current.
Q. Does cGMP change over time?
A. Yes.
Q. Did cGMP change with regard to nitrosamines in the 2019 time frame as far as the FDA is concerned?
MR. SLATER: Objection.
A. I would draw that conclusion from the public statements that we looked at earlier, 2018 and 2019, that as information was developed and better understood, the expectations rose and were still, in fact, rising at the time of the January 25, 2019

statement.
BY MR. FOX:
Q. And when cGMP changes, does the FDA typically apply it retroactively to the industry?
MR. SLATER: Objection.
You can answer.
A. No.
BY MR. FOX:
Q. That would be unfair, wouldn't it?
MR. SLATER: Objection.
You can answer.
A. Yes, it would be unfair, and that has not been the practice, to my knowledge.
MR. FOX: No further questions.
MR. SLATER: I don't have any other questions.
MR. FOX: Thank you, Mr. Chesney.
Thank you, Adam.
MR. SLATER: Thank you very much.

THE WITNESS: Thank you, Mr. Slater.

MR. SLATER: It was nice to meet you. I hope everybody has a nice evening.

THE WITNESS: Thank you. Same to you, sir.

THE VIDEOGRAPHER: The time is 5:03 p.m. We're off the record. This concludes today's deposition.

(Whereupon, the deposition was concluded.)

CERTIFICATE

I, MAUREEN O'CONNOR POLLARD, Registered Diplomate Reporter, Realtime Systems Administrator, and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the examination, DAVID L. CHESNEY, was remotely duly identified and sworn by me to testify to the truth, the whole truth, and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

____

MAUREEN O'CONNOR POLLARD
NCRA Registered Diplomate Reporter
Realtime Systems Administrator
Certified Shorthand Reporter
Notary Public

Dated: March 24, 2022

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I, ___________________________, do Hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
DAVID L. CHESNEY DATE

Subscribed and sworn
To before me this
______ day of _________________, 20____.

My commission expires: ________________

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Notary Public

LAWYER'S NOTES

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